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Abirtega, Zytiga



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-356191                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Guideline Name</b> | Abirtega, Zytiga                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 9/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                                                                 |                       |
|-----------------------------------------------------------------|-----------------------|
| Product Name: Brand Zytiga, Brand Abirtega, generic abiraterone |                       |
| Diagnosis                                                       | Prostate Cancer       |
| Approval Length                                                 | 12 month(s)           |
| Therapy Stage                                                   | Initial Authorization |

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Prior Authorization |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1 - Diagnosis of prostate cancer</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>2 - ONE of the following:</b></p> <p><b>2.1 Disease is metastatic</b></p> <p style="text-align: center;"><b>OR</b></p> <p><b>2.2 Disease is regional node positive (Any T, N1, M0)</b></p> <p style="text-align: center;"><b>OR</b></p> <p><b>2.3 Patient is in a very-high-risk group receiving external beam radiation therapy (EBRT)</b></p> <p style="text-align: center;"><b>OR</b></p> <p><b>2.4 Positive pelvic persistence/recurrence after prostatectomy</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>3 - Used in combination with prednisone or dexamethasone</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>4 - ONE of the following:</b></p> <p><b>4.1 Used in combination with a gonadotropin-releasing hormone (GnRH) analog [e.g., Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix)]</b></p> |                     |

**OR**

**4.2** Patient has had bilateral orchiectomy

**AND**

**5** - If the request is for the 500 mg (milligram) tablet, the prescriber provides a reason or special circumstance the patient cannot take abiraterone 250 mg

| Product Name:Brand Zytiga, Brand Abirtega, generic abiraterone                                                                                                                                                                                                                                                          |                     |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Diagnosis                                                                                                                                                                                                                                                                                                               | Prostate Cancer     |
| Approval Length                                                                                                                                                                                                                                                                                                         | 12 month(s)         |
| Therapy Stage                                                                                                                                                                                                                                                                                                           | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                                                                                          | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Patient does not show evidence of progressive disease while on the requested therapy</p> <p><b>AND</b></p> <p><b>2</b> - If the request is for the 500 mg tablet, the prescriber provides a reason or special circumstance the patient cannot take abiraterone 250 mg</p> |                     |

| Product Name:Brand Zytiga, Brand Abirtega, generic abiraterone |                       |
|----------------------------------------------------------------|-----------------------|
| Diagnosis                                                      | Salivary Gland Tumor  |
| Approval Length                                                | 12 month(s)           |
| Therapy Stage                                                  | Initial Authorization |
| Guideline Type                                                 | Prior Authorization   |

**Approval Criteria**

1 - Diagnosis of salivary gland tumor

**AND**

2 - Used in combination with prednisone

**AND**

3 - Androgen receptor positive recurrent disease

**AND**

4 - If the request is for the 500mg tablet, the prescriber provides a reason or special circumstance the patient cannot take abiraterone 250mg

|                                                                                                                                                                                                                                                                                                         |                      |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|
| Product Name: Brand Zytiga, Brand Abirtega, generic abiraterone                                                                                                                                                                                                                                         |                      |
| Diagnosis                                                                                                                                                                                                                                                                                               | Salivary Gland Tumor |
| Approval Length                                                                                                                                                                                                                                                                                         | 12 month(s)          |
| Therapy Stage                                                                                                                                                                                                                                                                                           | Reauthorization      |
| Guideline Type                                                                                                                                                                                                                                                                                          | Prior Authorization  |
| <p><b>Approval Criteria</b></p> <p>1 - Patient does not show evidence of progressive disease while on the requested therapy</p> <p><b>AND</b></p> <p>2 - If the request is for the 500mg tablet, the prescriber provides a reason or special circumstance the patient cannot take abiraterone 250mg</p> |                      |



|                                                                                                                                                                                                                                                                                                                                                      |                           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name: Brand Zytiga, Brand Abirtega, generic abiraterone                                                                                                                                                                                                                                                                                      |                           |
| Diagnosis                                                                                                                                                                                                                                                                                                                                            | NCCN Recommended Regimens |
| Approval Length                                                                                                                                                                                                                                                                                                                                      | 12 month(s)               |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                        | Initial Authorization     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                       | Prior Authorization       |
| <p><b>Approval Criteria</b></p> <p>1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - If the request is for the 500 mg tablet, the prescriber provides a reason or special circumstance the patient cannot take abiraterone 250 mg</p> |                           |

|                                                                                                                                                                                                                                                                                                                       |                           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name: Brand Zytiga, Brand Abirtega, generic abiraterone                                                                                                                                                                                                                                                       |                           |
| Diagnosis                                                                                                                                                                                                                                                                                                             | NCCN Recommended Regimens |
| Approval Length                                                                                                                                                                                                                                                                                                       | 12 month(s)               |
| Therapy Stage                                                                                                                                                                                                                                                                                                         | Reauthorization           |
| Guideline Type                                                                                                                                                                                                                                                                                                        | Prior Authorization       |
| <p><b>Approval Criteria</b></p> <p>1 - Documentation of positive clinical response to the requested therapy</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - If the request is for the 500 mg tablet, the prescriber provides a reason or special circumstance the patient cannot take abiraterone 250 mg</p> |                           |

## 2 . Revision History

| Date      | Notes                         |
|-----------|-------------------------------|
| 7/31/2025 | Updated formularies to add IN |

Acitretin



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-220211                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Guideline Name</b> | Acitretin                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 5/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                        |                       |
|------------------------|-----------------------|
| Product Name:acitretin |                       |
| Approval Length        | 12 month(s)           |
| Therapy Stage          | Initial Authorization |
| Guideline Type         | Prior Authorization   |

### Approval Criteria

1 - Diagnosis of severe psoriasis

**AND**

2 - Prescribed by or in consultation with a dermatologist

**AND**

3 - ONE of the following:

**3.1** Failure to a 3-month trial of methotrexate at the maximally indicated dose, as confirmed by claims history or submission of medical records

**OR**

**3.2** History of intolerance or contraindication to methotrexate (please specify intolerance or contraindication)

**AND**

4 - ONE of the following:

- Greater than or equal to 10% body surface area involvement
- Palmoplantar, facial, or genital involvement
- Severe scalp psoriasis

|                        |                     |
|------------------------|---------------------|
| Product Name:acitretin |                     |
| Approval Length        | 12 month(s)         |
| Therapy Stage          | Reauthorization     |
| Guideline Type         | Prior Authorization |

**Approval Criteria**

1 - Documentation of positive clinical response to the requested therapy

**2 . Revision History**

| Date      | Notes                                                                          |
|-----------|--------------------------------------------------------------------------------|
| 3/13/2025 | Updated formularies. Updated title. Removed prescriber requirement from reauth |

Actimmune



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-127780                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Guideline Name</b> | Actimmune                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 9/1/2023 |
|-----------------|----------|

## 1 . Criteria

|                        |                                     |
|------------------------|-------------------------------------|
| Product Name:Actimmune |                                     |
| Diagnosis              | Chronic Granulomatous Disease (CGD) |
| Approval Length        | 12 month(s)                         |
| Therapy Stage          | Initial Authorization               |
| Guideline Type         | Prior Authorization                 |

**Approval Criteria**

1 - Diagnosis of chronic granulomatous disease

**Product Name:Actimmune**

|           |               |
|-----------|---------------|
| Diagnosis | Osteopetrosis |
|-----------|---------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

1 - Diagnosis of severe, malignant osteopetrosis

**Product Name:Actimmune**

|           |                             |
|-----------|-----------------------------|
| Diagnosis | Primary Cutaneous Lymphomas |
|-----------|-----------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

1 - Patient has ONE of the following diagnoses:

- Mycosis fungoides (MF)
- Sézary syndrome (SS)

**Product Name:Actimmune**

|           |                                                                                 |
|-----------|---------------------------------------------------------------------------------|
| Diagnosis | Chronic Granulomatous Disease (CGD), Osteopetrosis, Primary Cutaneous Lymphomas |
|-----------|---------------------------------------------------------------------------------|

|                                                                                                                     |                     |
|---------------------------------------------------------------------------------------------------------------------|---------------------|
| Approval Length                                                                                                     | 12 month(s)         |
| Therapy Stage                                                                                                       | Reauthorization     |
| Guideline Type                                                                                                      | Prior Authorization |
| <b>Approval Criteria</b><br><br><b>1</b> - Patient does not show evidence of progressive disease while on Actimmune |                     |

|                                                                                                                                                |                           |
|------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Actimmune                                                                                                                         |                           |
| Diagnosis                                                                                                                                      | NCCN Recommended Regimens |
| Approval Length                                                                                                                                | 12 month(s)               |
| Therapy Stage                                                                                                                                  | Initial Authorization     |
| Guideline Type                                                                                                                                 | Prior Authorization       |
| <b>Approval Criteria</b><br><br><b>1</b> - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium |                           |

|                                                                                                             |                           |
|-------------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Actimmune                                                                                      |                           |
| Diagnosis                                                                                                   | NCCN Recommended Regimens |
| Approval Length                                                                                             | 12 month(s)               |
| Therapy Stage                                                                                               | Reauthorization           |
| Guideline Type                                                                                              | Prior Authorization       |
| <b>Approval Criteria</b><br><br><b>1</b> - Documentation of positive clinical response to Actimmune therapy |                           |

## 2 . Revision History



UnitedHealthcare Community Plan of New Jersey – Clinical Pharmacy Guidelines

| Date      | Notes                                                                                            |
|-----------|--------------------------------------------------------------------------------------------------|
| 7/10/2023 | Updated formularies, simplified and combined criteria, updated indications, cleaned up criteria. |

Adalimumab



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-219260                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Guideline Name</b> | Adalimumab                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 5/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                                                                                                                                           |                           |
|-------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name: Humira, Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi, Yuflyma, Yusimry, Adalimumab (all products) |                           |
| Diagnosis                                                                                                                                 | Rheumatoid Arthritis (RA) |
| Approval Length                                                                                                                           | 12 month(s)               |
| Therapy Stage                                                                                                                             | Initial Authorization     |
| Guideline Type                                                                                                                            | Prior Authorization       |

## **Approval Criteria**

**1** - Diagnosis of moderately to severely active rheumatoid arthritis

**AND**

**2** - Patient is not receiving adalimumab in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

**AND**

**3** - Prescribed by or in consultation with a rheumatologist

**AND**

**4** - ONE of the following:

**4.1** Patient is currently on Adalimumab therapy as confirmed by claims history or submission of medical records

**OR**

**4.2** BOTH of the following:

**4.2.1** ONE of the following:

- Failure to a 3 month trial of ONE non-biologic DMARD (e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine) at maximally indicated doses confirmed by claims history or submission of medical records
- History of intolerance or contraindication to one non-biologic DMARD (e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine) (please specify intolerance or contraindication)
- Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of rheumatoid arthritis as confirmed by claims history or submission of medical records [e.g., Cimzia (certolizumab), Simponi (golimumab), Olumiant (baricitinib), Rinvoq (upadacitinib), Xeljanz/Xeljanz XR (tofacitinib)]

**AND**

**4.2.2** If the request is for a non-preferred adalimumab product, ONE of the following:

- Failure of Tyenne (tocilizumab-aazg) confirmed by claims history or submitted medical records
- History of intolerance or contraindication to Tyenne (tocilizumab-aazg) [please specify intolerance or contraindication]

**AND**

**5** - If the request is for a non-preferred adalimumab product, the prescriber has given a clinical reason or special circumstance why the patient is unable to use the preferred adalimumab products (please document reason/special circumstances)\*

**AND**

**6** - If the request is for BRAND Humira, ONE of the following:

**6.1** Submission of medical records confirming patient allergy or intolerance to at least two preferred adalimumab biosimilars' inactive ingredients

**OR**

**6.2** BOTH of the following:

- Submission of medical records confirming patient has previously been successfully treated with brand Humira
- Submission of medical records confirming patient has tried at least two preferred adalimumab biosimilars for 6-8 weeks per product and saw a decrease in effectiveness

Notes

\*If approving a non-preferred adalimumab, please enter  
 1) The group authorization CSPREFADAL (for NY EPP and NY use: CSNYADAL)  
 2) An authorization for the non-preferred adalimumab at GPI-12 level  
  
 See PDL links in Background

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                    |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------|
| Product Name: Humira, Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi, Yuflyma, Yusimry, Adalimumab (all products)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                    |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Polyarticular Juvenile Idiopathic Arthritis (PJIA) |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | 12 month(s)                                        |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Initial Authorization                              |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Prior Authorization                                |
| <p><b>Approval Criteria</b></p> <p><b>1 - ALL of the following:</b></p> <p><b>1.1</b> Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis</p> <p style="text-align: center;"><b>AND</b></p> <p><b>1.2</b> Patient is not receiving adalimumab in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]</p> <p style="text-align: center;"><b>AND</b></p> <p><b>1.3</b> Prescribed by or in consultation with a rheumatologist</p> <p style="text-align: center;"><b>AND</b></p> <p><b>1.4</b> If the request is for a non-preferred adalimumab product, the prescriber has given a clinical reason or special circumstance why the patient is unable to use the preferred adalimumab products (please document reason/special circumstances)*</p> <p style="text-align: center;"><b>AND</b></p> <p><b>1.5</b> If the request is for a non-preferred adalimumab product, ONE of the following:</p> <ul style="list-style-type: none"> <li>• Failure of Tyenne (tocilizumab-aazg) confirmed by claims history or submitted medical records</li> </ul> |                                                    |

- History of intolerance or contraindication to Tyenne (tocilizumab-aazg) [please specify intolerance or contraindication]

**AND**

**1.6** If the request is for BRAND Humira, ONE of the following:

**1.6.1** Submission of medical records confirming patient allergy or intolerance to at least two preferred adalimumab biosimilars' inactive ingredients

**OR**

**1.6.2** BOTH of the following:

- Submission of medical records confirming patient has previously been successfully treated with brand Humira
- Submission of medical records confirming patient has tried at least two preferred adalimumab biosimilars for 6-8 weeks per product and saw a decrease in effectiveness

**OR**

**2** - ALL of the following:

**2.1** Patient is currently on Adalimumab therapy as confirmed by claims history or submission of medical records

**AND**

**2.2** Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis

**AND**

**2.3** Patient is not receiving adalimumab in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

**AND**

**2.4** Prescribed by or in consultation with a rheumatologist

**AND**

**2.5** If the request is for a non-preferred adalimumab product, the prescriber has given a clinical reason or special circumstance why the patient is unable to use the preferred adalimumab products (please document reason/special circumstances)\*

**AND**

**2.6** If the request is for BRAND Humira, ONE of the following:

**2.6.1** Submission of medical records confirming patient allergy or intolerance to at least two preferred adalimumab biosimilars' inactive ingredients

**OR**

**2.6.2** BOTH of the following:

- Submission of medical records confirming patient has previously been successfully treated with brand Humira
- Submission of medical records confirming patient has tried at least two preferred adalimumab biosimilars for 6-8 weeks per product and saw a decrease in effectiveness

|       |                                                                                                                                                                                                                                                             |
|-------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Notes | <p>*If approving a non-preferred adalimumab, please enter</p> <p>1) The group authorization CSPREFADAL (for NY EPP and NY use: CSNYADAL)</p> <p>2) An authorization for the non-preferred adalimumab at GPI-12 level</p> <p>See PDL links in Background</p> |
|-------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

Product Name: Humira, Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi, Yuflyma, Yusimry, Adalimumab (all products)

|           |                           |
|-----------|---------------------------|
| Diagnosis | Psoriatic Arthritis (PsA) |
|-----------|---------------------------|

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                       |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1 - Diagnosis of active psoriatic arthritis</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>2 - Patient is not receiving adalimumab in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>3 - Prescribed by or in consultation with one of the following:</b></p> <ul style="list-style-type: none"> <li>• Rheumatologist</li> <li>• Dermatologist</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>4 - ONE of the following:</b></p> <p><b>4.1 Patient is currently on Adalimumab therapy as confirmed by claims history or submission of medical records</b></p> <p style="text-align: center;"><b>OR</b></p> <p><b>4.2 ONE of the following:</b></p> <ul style="list-style-type: none"> <li>• Failure to a 3 month trial of methotrexate at the maximally indicated dose confirmed by claims history or submission of medical records</li> </ul> |                       |



- History of intolerance or contraindication to methotrexate (please specify intolerance or contraindication)
- Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of psoriatic arthritis as confirmed by claims history or submission of medical records [e.g., Cimzia (certolizumab), Simponi (golimumab), ustekinumab, Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), Otezla (apremilast), Skyrizi (risankizumab-rzaa)]

**AND**

**5** - If the request is for a non-preferred adalimumab product, the prescriber has given a clinical reason or special circumstance why the patient is unable to use the preferred adalimumab products (please document reason/special circumstances)\*

**AND**

**6** - If the request is for BRAND Humira, ONE of the following:

**6.1** Submission of medical records confirming patient allergy or intolerance to at least two preferred adalimumab biosimilars' inactive ingredients

**OR**

**6.2** BOTH of the following:

- Submission of medical records confirming patient has previously been successfully treated with brand Humira
- Submission of medical records confirming patient has tried at least two preferred adalimumab biosimilars for 6-8 weeks per product and saw a decrease in effectiveness

|       |                                                                                                                                                                                                                                                             |
|-------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Notes | <p>*If approving a non-preferred adalimumab, please enter</p> <p>1) The group authorization CSPREFADAL (for NY EPP and NY use: CSNYADAL)</p> <p>2) An authorization for the non-preferred adalimumab at GPI-12 level</p> <p>See PDL links in Background</p> |
|-------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

Product Name: Humira, Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi, Yuflyma, Yusimry, Adalimumab (all products)

|           |                  |
|-----------|------------------|
| Diagnosis | Plaque Psoriasis |
|-----------|------------------|

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                       |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1 - Diagnosis of moderate to severe chronic plaque psoriasis</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>2 - Patient is not receiving adalimumab in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>3 - Prescribed by or in consultation with a dermatologist</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>4 - ONE of the following:</b></p> <p><b>4.1 Patient is currently on Adalimumab therapy as confirmed by claims history or submission of medical records</b></p> <p style="text-align: center;"><b>OR</b></p> <p><b>4.2 ONE of the following:</b></p> <p><b>4.2.1 ALL of the following:</b></p> <p><b>4.2.1.1 Greater than or equal to 3% body surface area involvement, palmoplantar, facial, or genital involvement, or severe scalp psoriasis</b></p> |                       |

**AND**

**4.2.1.2** ONE of the following:

**4.2.1.2.1** Failure to ONE of the following topical therapy classes confirmed by claims history or submission of medical records:

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin
- Coal tar

**OR**

**4.2.1.2.2** History of intolerance or contraindication to ALL of the following topical therapy classes (please specify intolerance or contraindication):

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin
- Coal tar

**AND**

**4.2.1.3** ONE of the following:

**4.2.1.3.1** Failure to a 3 month trial of methotrexate at the maximally indicated dose confirmed by claims history or submission of medical records

**OR**

**4.2.1.3.2** History of intolerance or contraindication to methotrexate (please specify intolerance or contraindication)

**OR**

**4.2.2** Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of plaque psoriasis as confirmed by claims history or submission of medical records [e.g., Cimzia (certolizumab), Otezla (apremilast), Skyrizi (risankizumab-rzaa), ustekinumab, Tremfya (guselkumab)]

**AND**

**5** - If the request is for a non-preferred adalimumab product, the prescriber has given a clinical reason or special circumstance why the patient is unable to use the preferred adalimumab products (please document reason/special circumstances)\*

**AND**

**6** - If the request is for BRAND Humira, ONE of the following:

**6.1** Submission of medical records confirming patient allergy or intolerance to at least two preferred adalimumab biosimilars' inactive ingredients

**OR**

**6.2** BOTH of the following:

- Submission of medical records confirming patient has previously been successfully treated with brand Humira
- Submission of medical records confirming patient has tried at least two preferred adalimumab biosimilars for 6-8 weeks per product and saw a decrease in effectiveness

Notes

\*If approving a non-preferred adalimumab, please enter  
 1) The group authorization CSPREFADAL (for NY EPP and NY use: CSNYADAL)  
 2) An authorization for the non-preferred adalimumab at GPI-12 level  
 See PDL links in Background

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                             |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|
| Product Name: Humira, Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi, Yuflyma, Yusimry, Adalimumab (all products)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                             |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Ankylosing Spondylitis (AS) |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | 12 month(s)                 |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Initial Authorization       |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Prior Authorization         |
| <p><b>Approval Criteria</b></p> <p><b>1 - Diagnosis of active ankylosing spondylitis</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>2 - Patient is not receiving adalimumab in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>3 - Prescribed by or in consultation with a rheumatologist</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>4 - ONE of the following:</b></p> <p><b>4.1 Patient is currently on Adalimumab therapy as confirmed by claims history or submission of medical records</b></p> <p style="text-align: center;"><b>OR</b></p> <p><b>4.2 ONE of the following:</b></p> <p><b>4.2.1 Failure to two NSAIDs (e.g., ibuprofen, naproxen) at maximally indicated doses, each used for at least 4 weeks, as confirmed by claims history or submission of medical records</b></p> |                             |

**OR**

**4.2.2** History of intolerance or contraindication to TWO NSAIDs (e.g., ibuprofen, naproxen) (please specify intolerance or contraindication)

**OR**

**4.2.3** Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of ankylosing spondylitis as confirmed by claims history or submission of medical records [e.g., Cimzia (certolizumab), Simponi (golimumab), Xeljanz/Xeljanz XR (tofacitinib)]

**AND**

**5** - If the request is for a non-preferred adalimumab product, the prescriber has given a clinical reason or special circumstance why the patient is unable to use the preferred adalimumab products (please document reason/special circumstances)\*

**AND**

**6** - If the request is for BRAND Humira, ONE of the following:

**6.1** Submission of medical records confirming patient allergy or intolerance to at least two preferred adalimumab biosimilars' inactive ingredients

**OR**

**6.2** BOTH of the following:

- Submission of medical records confirming patient has previously been successfully treated with brand Humira
- Submission of medical records confirming patient has tried at least two preferred adalimumab biosimilars for 6-8 weeks per product and saw a decrease in effectiveness

Notes

\*If approving a non-preferred adalimumab, please enter  
1) The group authorization CSPREFADAL (for NY EPP and NY use:

|  |                                                                                                                      |
|--|----------------------------------------------------------------------------------------------------------------------|
|  | CSNYADAL)<br>2) An authorization for the non-preferred adalimumab at GPI-12 level<br><br>See PDL links in Background |
|--|----------------------------------------------------------------------------------------------------------------------|

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                       |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Humira, Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi, Yuflyma, Yusimry, Adalimumab (all products)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                       |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Crohn's Disease (CD)  |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1 - Diagnosis of moderately to severely active Crohn's disease</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>2 - Patient is not receiving adalimumab in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), ustekinumab, Skyrizi (risankizumab)]</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>3 - Prescribed by or in consultation with a gastroenterologist</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>4 - ONE of the following:</b></p> <p><b>4.1 Patient is currently on Adalimumab therapy as confirmed by claims history or submission of medical records</b></p> <p style="text-align: center;"><b>OR</b></p> |                       |

**4.2 ONE of the following:**

**4.2.1** Failure to ONE of the following conventional drugs or classes at maximally indicated doses, as confirmed by claims history or submitted medical records:

- Corticosteroids (e.g., prednisone, methylprednisolone, budesonide)
- Azathioprine (generic Imuran)
- 6-mercaptopurine (generic Purinethol)
- Methotrexate

**OR**

**4.2.2** History of intolerance or contraindication to ALL of the following conventional drugs or classes (please specify intolerance or contraindication):

- Corticosteroids (e.g., prednisone, methylprednisolone, budesonide)
- Azathioprine (generic Imuran)
- 6-mercaptopurine (generic Purinethol)
- Methotrexate

**OR**

**4.2.3** Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of Crohn's disease as confirmed by claims history or submission of medical records [e.g., Cimzia (certolizumab), ustekinumab]

**AND**

**5** - If the request is for a non-preferred adalimumab product, the prescriber has given a clinical reason or special circumstance why the patient is unable to use the preferred adalimumab products (please document reason/special circumstances)\*

**AND**

**6** - If the request is for BRAND Humira, ONE of the following:

**6.1** Submission of medical records confirming patient allergy or intolerance to at least two preferred adalimumab biosimilars' inactive ingredients



**OR**

**6.2 BOTH of the following:**

- Submission of medical records confirming patient has previously been successfully treated with brand Humira
- Submission of medical records confirming patient has tried at least two preferred adalimumab biosimilars for 6-8 weeks per product and saw a decrease in effectiveness

|       |                                                                                                                                                                                                                                                             |
|-------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Notes | <p>*If approving a non-preferred adalimumab, please enter</p> <p>1) The group authorization CSPREFADAL (for NY EPP and NY use: CSNYADAL)</p> <p>2) An authorization for the non-preferred adalimumab at GPI-12 level</p> <p>See PDL links in Background</p> |
|-------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

Product Name: Humira, Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi, Yuflyma, Yusimry, Adalimumab (all products)

|                 |                       |
|-----------------|-----------------------|
| Diagnosis       | Ulcerative Colitis    |
| Approval Length | 12 month(s)           |
| Therapy Stage   | Initial Authorization |
| Guideline Type  | Prior Authorization   |

**Approval Criteria**

**1** - Diagnosis of moderately to severely active ulcerative colitis

**AND**

**2** - Patient is not receiving adalimumab in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), ustekinumab, Skyrizi (risankizumab)]

**AND**

**3** - Prescribed by or in consultation with a gastroenterologist

**AND**

**4** - ONE of the following:

**4.1** Patient is currently on Adalimumab therapy as confirmed by claims history or submission of medical records

**OR**

**4.2** ONE of the following:

**4.2.1** Patient has had prior or concurrent inadequate response to a therapeutic course of oral corticosteroids and/or immunosuppressants (e.g., azathioprine, 6-mercaptopurine) as confirmed by claims history or submitted medical records

**OR**

**4.2.2** Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of ulcerative colitis as confirmed by claims history or submission medical records [e.g., Simponi (golimumab), ustekinumab, Xeljanz (tofacitinib)]

**AND**

**5** - If the request is for a non-preferred adalimumab product, the prescriber has given a clinical reason or special circumstance why the patient is unable to use the preferred adalimumab products (please document reason/special circumstances)\*

**AND**

**6** - If the request is for BRAND Humira, ONE of the following:

**6.1** Submission of medical records confirming patient allergy or intolerance to at least two preferred adalimumab biosimilars' inactive ingredients

**OR**

**6.2** BOTH of the following:

- Submission of medical records confirming patient has previously been successfully treated with brand Humira
- Submission of medical records confirming patient has tried at least two preferred adalimumab biosimilars for 6-8 weeks per product and saw a decrease in effectiveness

Notes

\*If approving a non-preferred adalimumab, please enter  
 1) The group authorization CSPREFADAL (for NY EPP and NY use: CSNYADAL)  
 2) An authorization for the non-preferred adalimumab at GPI-12 level  
  
 See PDL links in Background

Product Name: Humira, Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi, Yuflyma, Yusimry, Adalimumab (all products)

|                 |                               |
|-----------------|-------------------------------|
| Diagnosis       | Hidradenitis Suppurativa (HS) |
| Approval Length | 12 month(s)                   |
| Therapy Stage   | Initial Authorization         |
| Guideline Type  | Prior Authorization           |

### Approval Criteria

**1** - Diagnosis of moderate to severe hidradenitis suppurativa (i.e., Hurley Stage II or III)

**AND**

**2** - Patient is not receiving adalimumab in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olanercept (baricitinib), Rinvoq (upadacitinib)]

**AND**

**3** - Prescribed by or in consultation with a dermatologist

**AND**

**4** - ONE of the following:

**4.1** Patient is currently on Adalimumab therapy as confirmed by claims history or submission of medical records

**OR**

**4.2** ONE of the following:

**4.2.1** Failure to at least ONE oral antibiotic (e.g., doxycycline, clindamycin, rifampin) at maximally indicated doses, as confirmed by claims history or submission of medical records

**OR**

**4.2.2** History of intolerance or contraindication to at least ONE oral antibiotic (e.g., doxycycline, clindamycin, rifampin) (please specify intolerance or contraindication)

**OR**

**4.2.3** Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of hidradenitis suppurativa as confirmed by claims history or submitted medical records [e.g., Bimzelx (bimekizumab-bkzx), Cosentyx (secukinumab)]

**AND**

**5** - If the request is for a non-preferred adalimumab product, the prescriber has given a clinical reason or special circumstance why the patient is unable to use the preferred adalimumab products (please document reason/special circumstances)\*

**AND**

**6** - If the request is for BRAND Humira, ONE of the following:

**6.1** Submission of medical records confirming patient allergy or intolerance to at least two preferred adalimumab biosimilars' inactive ingredients

**OR**

**6.2** BOTH of the following:

- Submission of medical records confirming patient has previously been successfully treated with brand Humira
- Submission of medical records confirming patient has tried at least two preferred adalimumab biosimilars for 6-8 weeks per product and saw a decrease in effectiveness

|       |                                                                                                                                                                                                                                                             |
|-------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Notes | <p>*If approving a non-preferred adalimumab, please enter</p> <p>1) The group authorization CSPREFADAL (for NY EPP and NY use: CSNYADAL)</p> <p>2) An authorization for the non-preferred adalimumab at GPI-12 level</p> <p>See PDL links in Background</p> |
|-------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                                                                                                                                          |                       |
|------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Humira, Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi, Yuflyma, Yusimry, Adalimumab (all products) |                       |
| Diagnosis                                                                                                                                | Uveitis (UV)          |
| Approval Length                                                                                                                          | 12 month(s)           |
| Therapy Stage                                                                                                                            | Initial Authorization |
| Guideline Type                                                                                                                           | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of non-infectious uveitis</p>                                                    |                       |

**AND**

**2** - Uveitis is classified as ONE of the following:

- Intermediate
- Posterior
- Panuveitis

**AND**

**3** - Patient is not receiving adalimumab in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

**AND**

**4** - Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Ophthalmologist

**AND**

**5** - ONE of the following:

**5.1** Patient is currently on Adalimumab therapy as confirmed by claims history or submission of medical records

**OR**

**5.2** BOTH of the following:

**5.2.1** ONE of the following:

**5.2.1.1** Failure to at least ONE corticosteroid (e.g., prednisolone, prednisone) at maximally indicated dose, as confirmed by claims history or submission of medical records

**OR**

**5.2.1.2** History of intolerance or contraindication to at least ONE corticosteroid (e.g., prednisolone, prednisone) (please specify intolerance or contraindication)

**AND**

**5.2.2** ONE of the following:

**5.2.2.1** Failure to at least ONE systemic non-biologic immunosuppressant (e.g., methotrexate, cyclosporine, azathioprine, mycophenolate) at maximally indicated dose, as confirmed by claims history or submission of medical records

**OR**

**5.2.2.2** History of intolerance or contraindication to at least ONE systemic non-biologic immunosuppressant (e.g., methotrexate, cyclosporine, azathioprine, mycophenolate) (please specify intolerance or contraindication)

**AND**

**6** - If the request is for a non-preferred adalimumab product, the prescriber has given a clinical reason or special circumstance why the patient is unable to use the preferred adalimumab products (please document reason/special circumstances)\*

**AND**

**7** - If the request is for BRAND Humira, ONE of the following:

**7.1** Submission of medical records confirming patient allergy or intolerance to at least two preferred adalimumab biosimilars' inactive ingredients

**OR**

**7.2** BOTH of the following:

|                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                             |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"> <li>Submission of medical records confirming patient has previously been successfully treated with brand Humira</li> <li>Submission of medical records confirming patient has tried at least two preferred adalimumab biosimilars for 6-8 weeks per product and saw a decrease in effectiveness</li> </ul> |                                                                                                                                                                                                                                                             |
| Notes                                                                                                                                                                                                                                                                                                                                         | <p>*If approving a non-preferred adalimumab, please enter</p> <p>1) The group authorization CSPREFADAL (for NY EPP and NY use: CSNYADAL)</p> <p>2) An authorization for the non-preferred adalimumab at GPI-12 level</p> <p>See PDL links in Background</p> |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                     |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------|
| Product Name: Humira, Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi, Yuflyma, Yusimry, Adalimumab (all products)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                     |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | RA, PJIA, PsA, Plaque Psoriasis, AS, CD, Ulcerative Colitis, HS, UV |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 12 month(s)                                                         |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Reauthorization                                                     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Prior Authorization                                                 |
| <p><b>Approval Criteria</b></p> <p>1 - Documentation of positive clinical response to Adalimumab therapy</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Patient is not receiving adalimumab in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]^</p> <p style="text-align: center;"><b>AND</b></p> <p>3 - If the request is for a non-preferred adalimumab product, the prescriber has given a clinical reason or special circumstance why the patient is unable to use the preferred adalimumab products (please document reason/special circumstances)*</p> |                                                                     |



**AND**

**4** - If the request is for BRAND Humira, ONE of the following:

**4.1** Submission of medical records confirming patient allergy or intolerance to at least two preferred adalimumab biosimilars' inactive ingredients

**OR**

**4.2** BOTH of the following:

- Submission of medical records confirming patient has previously been successfully treated with brand Humira
- Submission of medical records confirming patient has tried at least two preferred adalimumab biosimilars for 6-8 weeks per product and saw a decrease in effectiveness

Notes

\*If approving a non-preferred adalimumab, please enter  
 1) The group authorization CSPREFADAL (for NY EPP and NY use: CSNYADAL)  
 2) An authorization for the non-preferred adalimumab at GPI-12 level  
  
 See PDL links in Background  
 ^ Examples of drug(s) may not be applicable based on the requested indication.

## 2 . Background

### Benefit/Coverage/Program Information

#### PDL links

CO: <https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html>

HI: <https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html>

|                                                                                                                                                                                                                                                                                        |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| MD: <a href="https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-cp-pharmacy.html</a>                                    |
| NJ: <a href="https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html</a>                                |
| NM: <a href="https://www.uhcprovider.com/en/health-plans-by-state/new-mexico-health-plans/nm-comm-plan-home/nm-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/new-mexico-health-plans/nm-comm-plan-home/nm-cp-pharmacy.html</a>                                |
| NY/NY EPP: <a href="https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html</a>                             |
| PA CHIP: <a href="https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP">https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP</a> |
| RI: <a href="https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html</a>                            |

### 3 . Revision History

| Date      | Notes                                    |
|-----------|------------------------------------------|
| 3/17/2025 | Added criteria for brand Humira requests |

Adbry



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-228273                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Guideline Name</b> | Adbry                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 6/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                    |                       |
|--------------------|-----------------------|
| Product Name:Adbry |                       |
| Approval Length    | 12 month(s)           |
| Therapy Stage      | Initial Authorization |
| Guideline Type     | Prior Authorization   |

## **Approval Criteria**

**1** - Diagnosis of moderate to severe chronic atopic dermatitis

**AND**

**2** - ONE of the following:

**2.1** Failure to TWO of the following therapeutic classes of topical therapies, confirmed by claims history or submission of medical records:

- One medium, high or very-high potency topical corticosteroid [e.g., mometasone furoate (generic Elocon), fluocinolone acetonide (generic Synalar), fluocinonide (generic Lidex)] (see Table 1 in Background)
- One topical calcineurin inhibitor [e.g., pimecrolimus (generic Elidel), tacrolimus (generic Protopic)]
- Eucrisa (crisaborole)

**OR**

**2.2** History of intolerance or contraindication to ALL of the following therapeutic classes of topical therapies (please specify intolerance or contraindication):

- One medium, high or very-high potency topical corticosteroid [e.g., mometasone furoate (generic Elocon), fluocinolone acetonide (generic Synalar), fluocinonide (generic Lidex)] (see Table 1 in Background)
- One topical calcineurin inhibitor [e.g., pimecrolimus (generic Elidel), tacrolimus (generic Protopic)]
- Eucrisa (crisaborole)

**OR**

**2.3** Patient is currently on Adbry therapy as confirmed by claims history or submission of medical records

**AND**

**3** - Patient is NOT receiving Adbry in combination with EITHER of the following:

- Biologic immunomodulator [e.g., Dupixent (dupilumab), Ebglyss (lebrikizumab-lbkz), Nemluvio (nemolizumab-ilto)]
- Janus kinase inhibitor [e.g., Cibinqo (abrocitinib), Opzelura (topical ruxolitinib), Rinvoq (upadacitinib), Xeljanz/XR (tofacitinib)]

**AND**

**4** - Prescribed by or in consultation with ONE of the following:

- Dermatologist
- Allergist
- Immunologist

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                     |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Adbry                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                     |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 12 month(s)         |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of positive clinical response to Adbry therapy</p> <p><b>AND</b></p> <p><b>2</b> - Patient is NOT receiving Adbry in combination with either of the following:</p> <ul style="list-style-type: none"> <li>• Biologic immunomodulator [e.g., Dupixent (dupilumab), Ebglyss (lebrikizumab-lbkz), Nemluvio (nemolizumab-ilto)]</li> <li>• Janus kinas inhibitor [e.g., Cibinqo (abrocitinib), Opzelura (topical ruxolitinib), Rinvoq (upadacitinib), Xeljanz/XR (tofacitinib)]</li> </ul> <p><b>AND</b></p> <p><b>3</b> - Prescribed by or in consultation with ONE of the following:</p> |                     |

- Dermatologist
- Allergist
- Immunologist

## 2 . Background

### Benefit/Coverage/Program Information

**Table 1. Relative potencies of topical corticosteroids**

| Class             | Drug                                 | Dosage Form                     | Strength (%) |
|-------------------|--------------------------------------|---------------------------------|--------------|
| Very high potency | Augmented betamethasone dipropionate | Ointment, gel                   | 0.05         |
|                   | Clobetasol propionate                | Cream, foam, ointment           | 0.05         |
|                   | Diflorasone diacetate                | Ointment                        | 0.05         |
|                   | Halobetasol propionate               | Cream, ointment                 | 0.05         |
| High Potency      | Amcinonide                           | Cream, lotion, ointment         | 0.1          |
|                   | Augmented betamethasone dipropionate | Cream, lotion                   | 0.05         |
|                   | Betamethasone dipropionate           | Cream, foam, ointment, solution | 0.05         |
|                   | Desoximetasone                       | Cream, ointment                 | 0.25         |
|                   | Desoximetasone                       | Gel                             | 0.05         |
|                   | Diflorasone diacetate                | Cream                           | 0.05         |
|                   | Fluocinonide                         | Cream, gel, ointment, solution  | 0.05         |
|                   | Halcinonide                          | Cream, ointment                 | 0.1          |
|                   | Mometasone furoate                   | Ointment                        | 0.1          |
|                   | Triamcinolone acetonide              | Cream, ointment                 | 0.5          |

|                      |                            |                                   |              |
|----------------------|----------------------------|-----------------------------------|--------------|
| Medium potency       | Betamethasone valerate     | Cream, foam, lotion, ointment     | 0.1          |
|                      | Clocortolone pivalate      | Cream                             | 0.1          |
|                      | Desoximetasone             | Cream                             | 0.05         |
|                      | Fluocinolone acetonide     | Cream, ointment                   | 0.025        |
|                      | Flurandrenolide            | Cream, ointment, lotion           | 0.05         |
|                      | Fluticasone propionate     | Cream                             | 0.05         |
|                      | Fluticasone propionate     | Ointment                          | 0.005        |
|                      | Mometasone furoate         | Cream, lotion                     | 0.1          |
|                      | Triamcinolone acetonide    | Cream, ointment, lotion           | 0.1          |
| Lower-medium potency | Hydrocortisone butyrate    | Cream, ointment, solution         | 0.1          |
|                      | Hydrocortisone probutate   | Cream                             | 0.1          |
|                      | Hydrocortisone valerate    | Cream, ointment                   | 0.2          |
|                      | Prednicarbate              | Cream                             | 0.1          |
| Low potency          | Alclometasone dipropionate | Cream, ointment                   | 0.05         |
|                      | Desonide                   | Cream, gel, foam, ointment        | 0.05         |
|                      | Fluocinolone acetonide     | Cream, solution                   | 0.01         |
| Lowest potency       | Dexamethasone              | Cream                             | 0.1          |
|                      | Hydrocortisone             | Cream, lotion, ointment, solution | 0.25, 0.5, 1 |
|                      | Hydrocortisone acetate     | Cream, ointment                   | 0.5-1        |

### 3 . Revision History

| Date     | Notes                                                                                                                                                                       |
|----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 4/2/2025 | Updated formularies. Removed step through Dupixent, updated prescriber requirement to allow for consultation. Updated examples in safety check to add Ebglyss and Nemludio. |





ADHD Products



## Prior Authorization Guideline

|                       |                                                                                                         |
|-----------------------|---------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-409189                                                                                               |
| <b>Guideline Name</b> | ADHD Products                                                                                           |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>Medicaid - Community &amp; State New Jersey (PSI2300)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 11/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                 |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------|
| Product Name:generic amphetamine/dextroamphetamine salts (generic Adderall), generic amphetamine/dextroamphetamine salts ER (generic Adderall XR), generic methylphenidate ER tabs (generic Concerta), generic methylphenidate ER cp24 20mg, 30mg, and 40mg (generic Ritalin LA), generic methylphenidate ER tabs (generic Metadate ER), generic methylphenidate tabs (generic Ritalin), generic methylphenidate ER (CD) caps (generic Metadate CD), generic dexamethylphenidate, generic dexamethylphenidate ER, generic dextroamphetamine ER, generic dextroamphetamine 5 mg and 10 mg |                                                                                 |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Requests for Patients greater than or equal to the Maximum Age Edit of 18 years |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 12 month(s)                                                                     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Prior Authorization                                                             |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                 |

**Approval Criteria**

**1** - Patient has Attention Deficit Hyperactivity Disorder/Attention Deficit Disorder (ADHD/ADD)

**OR**

**2** - Patient has depression

**OR**

**3** - Patient has narcolepsy

**OR**

**4** - Patient has other hypersomnia of central origin

**OR**

**5** - Patient has Autism Spectrum Disorder

**OR**

**6** - Patient has mental fatigue secondary to traumatic brain injury (e.g., post-concussion syndrome)

**OR**

**7** - Patient has fatigue associated with medical illness in palliative or end of life care

**OR**

**8** - Patient has fatigue associated with multiple sclerosis

**OR**

**9 - BOTH of the following:**

**9.1** The use of this drug is supported by information from ONE of the following appropriate compendia of current literature:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopoeia-National Formulary (USP-NF)

**AND**

**9.2** The drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plans' program

|                                                                                                                                                                                                                                                                                                                                                                                   |                                               |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|
| Product Name:generic lisdexamfetamine capsules (generic Vyvanse capsule)                                                                                                                                                                                                                                                                                                          |                                               |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                         | Patient age greater than or equal to 18 years |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                   | 12 month(s)                                   |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                    | Prior Authorization                           |
| <p><b>Approval Criteria</b></p> <p><b>1 - Patient is 18 years of age or older</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>2 - ONE of the following:</b></p> <p><b>2.1 BOTH of the following:</b></p> <p><b>2.1.1 Diagnosis of ONE of the following:</b></p> <p><b>2.1.1.1 Attention Deficit Hyperactivity Disorder/Attention Deficit Disorders (ADHD/ADD)</b></p> |                                               |

**OR**

**2.1.1.2** Depression

**OR**

**2.1.1.3** Narcolepsy

**OR**

**2.1.1.4** Other hypersomnia of central origin

**OR**

**2.1.1.5** Autism Spectrum Disorder

**OR**

**2.1.1.6** Mental fatigue secondary to traumatic brain injury (e.g., post-concussion syndrome)

**OR**

**2.1.1.7** Fatigue associated with medical illness in patients in palliative or end of life care

**OR**

**2.1.1.8** Fatigue associated with multiple sclerosis

**OR**

**2.1.1.9** BOTH of the following:

**2.1.1.9.1** The use of this drug is supported by information from ONE of the following appropriate compendia:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopoeia-National Formulary (USP-NF)

**AND**

**2.1.1.9.2** The drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plans' program

**AND**

**2.1.2** ONE of the following:

**2.1.2.1** Failure to ONE of the following as confirmed by claims history or submission of medical records^:

- Amphetamine/dextroamphetamine salts extended-release (generic Adderall XR)
- Methylphenidate extended-release tablet or capsule (e.g., generic Concerta or Metadate CD)
- Dexmethylphenidate ER capsule (generic Focalin XR)

**OR**

**2.1.2.2** History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication)^:

- Amphetamine/dextroamphetamine salts extended-release (generic Adderall XR)
- Methylphenidate extended-release tablet or capsule (e.g., generic Concerta or Metadate CD)
- Dexmethylphenidate ER capsule (generic Focalin XR)

**OR**

**2.1.2.3** History of, or potential for, a substance abuse disorder

**OR**

## 2.2 Diagnosis of Binge Eating Disorder (BED)

|       |                                                                                 |
|-------|---------------------------------------------------------------------------------|
| Notes | ^NJ Psych Panel (any mental health prescriber) is not subject to this criteria. |
|-------|---------------------------------------------------------------------------------|

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|
| Product Name:generic lisdexamfetamine capsules (generic Vyvanse capsule)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Patient age less than 18 years |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | 12 month(s)                    |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Prior Authorization            |
| <p><b>Approval Criteria</b></p> <p>1 - Patient is less than 18 years of age</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - ONE of the following:</p> <p><b>2.1</b> Failure to ONE of the following as confirmed by claims history or submission of medical records^:</p> <ul style="list-style-type: none"> <li>amphetamine/dextroamphetamine salts extended-release (generic Adderall XR)</li> <li>methylphenidate extended-release tablet or capsule (e.g., generic Concerta or Metadate CD)</li> <li>dexmethylphenidate ER capsule (generic Focalin XR)</li> </ul> <p style="text-align: center;"><b>OR</b></p> <p><b>2.2</b> History of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance)^:</p> <ul style="list-style-type: none"> <li>amphetamine/dextroamphetamine salts extended-release (generic Adderall XR)</li> <li>methylphenidate extended-release tablet or capsule (e.g., generic Concerta or Metadate CD)</li> </ul> |                                |

- dexmethylphenidate ER capsule (generic Focalin XR)

OR

**2.3** History of, or potential for, a substance abuse disorder

OR

**2.4** Diagnosis of Binge Eating Disorder (BED)

|       |                                                                                 |
|-------|---------------------------------------------------------------------------------|
| Notes | ^NJ Psych Panel (any mental health prescriber) is not subject to this criteria. |
|-------|---------------------------------------------------------------------------------|

Product Name:(All) Brand Adderall, generic amphetamine/dextroamphetamine, Brand Adderall XR, generic amphetamine/dextroamphetamine ER, Brand Intuniv, generic guanfacine ER, generic methylphenidate ER tab, Brand Metadate CD, generic methylphenidate ER (CD), Brand Concerta, generic methylphenidate ER OSM, (generic Concerta), Brand Ritalin, generic methylphenidate tablet, Brand Ritalin LA, generic methylphenidate ER (LA), Brand Strattera, generic atomoxetine, Brand Vyvanse chewable tablets, Brand Vyvanse capsules, generic lisdexamfetamine chewable tablet, generic lisdexamfetamine capsules, Adzenys XR-ODT, Brand Amphetamine ER ODT, Brand Aptensio XR, generic methylphenidate ER (XR) cap, Cotempla XR-ODT, Brand Daytrana, generic methylphenidate patch, Brand Desoxyn, generic methamphetamine, Brand Dexedrine, generic dextroamphetamine ER, Dyanavel XR, Brand Evekeo, generic amphetamine, Brand Focalin, generic dexmethylphenidate, Brand Focalin XR, generic dexmethylphenidate ER, Jornay PM, Brand Kapvay, generic clonidine ER, Brand Methylin, generic methylphenidate soln, methylphenidate chew tabs, Brand Mydayis, generic amphetamine/dextroamphetamine ER (generic Mydayis), Brand Procentra, generic dextroamphetamine soln, Quillichew ER, Quillivant XR, Brand Zenzedi, generic dextroamphetamine, Brand Relexxii, Brand Methylphenidate ER OSM, generic methylphenidate ER OSM (generic Relexxii), Qelbree, Azstarys, Xelstryl, Onyda XR

|                 |                                                 |
|-----------------|-------------------------------------------------|
| Diagnosis       | Members Less than the FDA Approved Minimum Age* |
| Approval Length | 12 month(s)                                     |
| Guideline Type  | Prior Authorization                             |

### Approval Criteria

**1** - ONE of the following:

**1.1** Diagnosis of Attention Deficit Hyperactivity Disorder/Attention Deficit Disorder (ADHD/ADD)

**OR**

**1.2** The use of this drug is supported by information from ONE of the following appropriate compendia of current literature:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopoeia-National Formulary (USP-NF)

**AND**

**2** - The child is unresponsive to, or has had an inadequate response to behavioral therapy

**AND**

**3** - The child is experiencing moderate-severe continuing disturbance in function despite behavioral therapy

**AND**

**4** - ONE of the following<sup>^\*\*</sup>:

**4.1** If the request is for a preferred product, the patient has history of ONE of the following:

**4.1.1** Failure to THREE preferred alternatives approved for use in the patient's age, as confirmed by claims history or submission of medical records (In instances where there are fewer than three preferred alternatives approved for use in the patient's age, the patient must have a history of failure to ALL of the preferred products for the patient's age as confirmed by claims history or submission of medical records)

**OR**

**4.1.2** Contraindication or intolerance to THREE preferred alternatives approved for use in



the patient's age (In instances where there are fewer than three preferred alternatives approved for use in the patient's age, the patient must have a history of contraindication or intolerance to ALL of the preferred products for the patient's age) (please specify contraindication or intolerance)

**OR**

**4.2** If the request is for a non-preferred product, non-preferred criteria must also be met\*\*\*

|       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|-------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Notes | <p>*See Table 1 in background section for FDA approved min ages.<br/> ** PDL link: <a href="https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html</a>. Prior trials of formulary/PDL alternatives must sufficiently demonstrate that the formulary/PDL alternatives are either ineffective or inappropriate at the time of the request.<br/> ***For non-preferred criteria, please reference the Non-Preferred section below.<br/> ^NJ Psych Panel (any mental health prescriber) is not subject to this criteria.</p> |
|-------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                     |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name: Qelbree                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                     |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Non-Preferred       |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | 12 month(s)         |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - The patient has been receiving treatment with the requested non-preferred behavioral health medication and is new to the plan (enrollment effective date within the past 90 days)</p> <p><b>OR</b></p> <p><b>2</b> - The patient is currently receiving treatment with the requested non-preferred behavioral health medication in the hospital and must continue upon discharge</p> <p><b>OR</b></p> <p><b>3</b> - ALL of the following:</p> |                     |

**3.1 Diagnosis of Attention Deficit Hyperactivity Disorder/Attention Deficit Disorders (ADHD/ADD)**

**AND**

**3.2 ONE of the following^:**

**3.2.1** Failure to ALL of the following, as confirmed by claims history or submission of medical records:

- guanfacine ER (generic Intuniv)
- atomoxetine (generic Strattera)
- clonidine ER (generic Kapvay)

**OR**

**3.2.2** History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication):

- guanfacine ER (generic Intuniv)
- atomoxetine (generic Strattera)
- clonidine ER (generic Kapvay)

**AND**

**3.3 ONE of the following^:**

**3.3.1** Failure to ONE of the following, as confirmed by claims history or submission of medical records:

- Amphetamine/dextroamphetamine extended-release capsule (generic Adderall XR)
- Methylphenidate extended-release tablet (generic Concerta)
- Methylphenidate extended-release capsule (generic Metadate CD)
- Methylphenidate 20 mg (milligrams), 30 mg, 40 mg extended-release capsule (generic Ritalin LA)
- Dexmethylphenidate ER capsule (generic Focalin XR)
- Lisdexamfetamine dimesylate capsule (generic Vyvanse)

**OR**

**3.3.2** History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication):

- Amphetamine/dextroamphetamine extended-release capsule (generic Adderall XR)
- Methylphenidate extended-release tablet (generic Concerta)
- Methylphenidate extended-release capsule (generic Metadate CD)
- Methylphenidate 20 mg, 30 mg, 40 mg extended-release capsule (generic Ritalin LA)
- Dexmethylphenidate ER capsule (generic Focalin XR)
- Lisdexamfetamine dimesylate capsule (generic Vyvanse)

**OR**

**3.3.3** Physician attestation that use of a stimulant medication is not appropriate for the patient

|       |                                                                                 |
|-------|---------------------------------------------------------------------------------|
| Notes | ^NJ Psych Panel (any mental health prescriber) is not subject to this criteria. |
|-------|---------------------------------------------------------------------------------|

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                     |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name: Onyda XR                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                     |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Non-Preferred       |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 12 month(s)         |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - The patient has been receiving treatment with the requested non-preferred behavioral health medication and is new to the plan (enrollment effective date within the past 90 days)</p> <p><b>OR</b></p> <p><b>2</b> - The patient is currently receiving treatment with the requested non-preferred behavioral health medication in the hospital and must continue upon discharge</p> <p><b>OR</b></p> <p><b>3</b> - BOTH of the following:</p> |                     |

**3.1 Diagnosis of Attention Deficit Hyperactivity Disorder/Attention Deficit Disorders (ADHD/ADD)**

**AND**

**3.2 ONE of the following^:**

- Failure to clonidine ER tablet (generic Kapvay) as confirmed by claims history or submission of medical records
- History of contraindication or intolerance to clonidine ER tablet (generic Kapvay) (please specify contraindication or intolerance)

|       |                                                                                     |
|-------|-------------------------------------------------------------------------------------|
| Notes | ^NJ Psych Panel (any mental health prescriber) is not subject to this c<br>riteria. |
|-------|-------------------------------------------------------------------------------------|

Product Name: Brand Adderall, Brand Adderall XR, Adzenys XR-ODT, Brand Amphetamine ER ODT, Brand Aptensio XR, generic methylphenidate ER (XR) cap (generic Aptensio XR), Brand Concerta, Cotempla XR-ODT, Brand Daytrana, generic methylphenidate patch, Brand Desoxyn, generic methamphetamine, Brand Dexedrine, Dyanavel XR, Brand Evekeo, generic amphetamine, Brand Focalin, Brand Focalin XR, Brand Intuniv, Jornay PM, Brand Metadate CD, Brand Methylin, generic methylphenidate soln, methylphenidate chew tabs, Brand Mydayis, generic amphetamine/dextroamphetamine ER (generic Mydayis), Brand Procentra, generic dextroamphetamine soln, Quillichew ER, Quillivant XR, Brand Relexxii, Brand Methylphenidate ER OSM, generic methylphenidate ER OSM (generic Relexxii), Brand Ritalin, Brand Ritalin LA, generic methylphenidate ER (LA) 10 mg and 60 mg caps, Brand Strattera, Brand Zenzedi, generic dextroamphetamine 2.5 mg, 7.5 mg, 15 mg, 20 mg and 30 mg, Azstarys, Xelstryl

|                 |                     |
|-----------------|---------------------|
| Diagnosis       | Non-Preferred*      |
| Approval Length | 12 month(s)         |
| Guideline Type  | Prior Authorization |

**Approval Criteria**

**1** - The patient has been receiving treatment with the requested non-preferred behavioral health medication and is new to the plan (enrollment effective date within the past 90 days)

**OR**

**2** - The patient is currently receiving treatment with the requested non-preferred behavioral health medication in the hospital and must continue upon discharge

**OR**

**3** - If the request is non-preferred\*, ALL of the following:

**3.1** The patient has a history of ONE of the following^:

**3.1.1** Failure to a majority (not more than three) of the preferred\* formulary/PDL alternatives for the given diagnosis, as confirmed by claims history or submission of medical records (In instances where there are fewer than three preferred alternatives, the patient must have a history of failure to ALL of the preferred products for the patient's age as confirmed by claims history or submission of medical records)

**OR**

**3.1.2** Contraindication or intolerance to a majority (not more than three) of the preferred\* formulary/PDL alternatives for the given diagnosis (In instances where there are fewer than three preferred alternatives, the patient must have a history of contraindication or intolerance to ALL of the preferred products for the patient's age) (please specify contraindication or intolerance)

**AND**

**3.2** If the request is for a multi-source brand medication, ONE of the following^:

**3.2.1** The multi-source brand is being requested because of an adverse reaction, allergy, or sensitivity to a generic equivalent (specify the adverse reaction, allergy or sensitivity)

**OR**

**3.2.2** The multi-source brand is being requested due to a therapeutic failure with the generic equivalent, as documented by submission of medical records

**OR**

**3.2.3** The multi-source brand is being requested because transition to a generic equivalent could result in destabilization of the patient

**OR**

**3.2.4** Special clinical circumstances exist that preclude the use of a generic version of the multi-source brand medication for the patient (document special clinical circumstances)

**AND**

**3.3** ONE of the following:

**3.3.1** The requested drug must be used for an FDA (Food and Drug Administration)-approved indication

**OR**

**3.3.2** BOTH of the following:

**3.3.2.1** The use of this drug is supported by information from ONE of the following appropriate compendia of current literature:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopoeia-National Formulary (USP-NF)

**AND**

**3.3.2.2** The drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plans' program

|       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|-------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Notes | <p>*PDL link: <a href="https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html</a></p> <p>*Prior trials of formulary/PDL alternatives must sufficiently demonstrate that the formulary/PDL alternatives are either ineffective or inappropriate at the time of the request.</p> <p>^NJ Psych Panel (any mental health prescriber) is not subject to this criteria.</p> |
|-------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                     |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name: Brand Vyvanse capsules, Brand Vyvanse chewable tablet, generic lisdexamfetamine chewable tablet                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                     |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | ADHD/ADD            |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 12 month(s)         |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - The patient has been receiving treatment with the requested non-preferred behavioral health medication and is new to the plan (enrollment effective date within the past 90 days)</p> <p style="text-align: center;"><b>OR</b></p> <p><b>2</b> - The patient is currently receiving treatment with the requested non-preferred behavioral health medication in the hospital and must continue upon discharge</p> <p style="text-align: center;"><b>OR</b></p> <p><b>3</b> - ALL of the following:</p> <p><b>3.1</b> Diagnosis of Attention Deficit Hyperactivity Disorder/Attention Deficit Disorders (ADHD/ADD)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3.2</b> ONE of the following^:</p> <p><b>3.2.1</b> Failure to ALL of the following as confirmed by claims history or submission of medical records:</p> <ul style="list-style-type: none"> <li>• Amphetamine/dextroamphetamine salts extended-release (generic Adderall XR)</li> <li>• Methylphenidate extended-release tablet or capsule (e.g., generic Concerta or Metadate CD)</li> <li>• Dexmethylphenidate ER capsule (generic Focalin XR)</li> </ul> |                     |

**OR**

**3.2.2** History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication):

- Amphetamine/dextroamphetamine salts extended-release (generic Adderall XR)
- Methylphenidate extended-release tablet or capsule (e.g., generic Concerta or Metadate CD)
- Dexmethylphenidate ER capsule (generic Focalin XR)

**OR**

**3.2.3** BOTH of the following:

**3.2.3.1** History of, or potential for, a substance abuse disorder

**AND**

**3.2.3.2** ONE of the following:

- Failure to atomoxetine (generic Strattera) as confirmed by claims history or submission of medical records
- History of intolerance or contraindication to atomoxetine (generic Strattera) (please specify intolerance or contraindication)

**AND**

**3.3** If the request is for BRAND Vyvanse capsules or BRAND Vyvanse chewable tablets, ONE of the following<sup>^\*</sup>:

**3.3.1** The multi-source brand is being requested because of an adverse reaction, allergy, or sensitivity to a generic equivalent (specify the adverse reaction, allergy or sensitivity)

**OR**

**3.3.2** The multi-source brand is being requested due to a therapeutic failure with the generic equivalent, as documented by submission of medical records



**OR**

**3.3.3** The multi-source brand is being requested because transition to a generic equivalent could result in destabilization of the patient

**OR**

**3.3.4** Special clinical circumstances exist that preclude the use of a generic version of the multi-source brand medication for the patient (document special clinical circumstances)

|       |                                                                                                                                                                                                                                                                                                                     |
|-------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Notes | <p>^NJ Psych Panel (any mental health prescriber) is not subject to this criteria.</p> <p>* Generic Vyvanse became available 9/2023. Requests for members currently on brand Vyvanse should be evaluated for use of the GENE RIC, unless the provider provides specific rationale for ongoing use of the brand.</p> |
|-------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

Product Name: Brand Vyvanse capsules, Brand Vyvanse chewable tablet, generic lisdexamfetamine chewable tablet

|           |                        |
|-----------|------------------------|
| Diagnosis | Non-ADHD/ADD Diagnoses |
|-----------|------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

### Approval Criteria

**1** - The patient has been receiving treatment with the requested non-preferred behavioral health medication and is new to the plan (enrollment effective date within the past 90 days)

**OR**

**2** - The patient is currently receiving treatment with the requested non-preferred behavioral health medication in the hospital and must continue upon discharge

**OR**

**3 - ONE of the following:**

**3.1 ALL of the following:**

**3.1.1 ONE of the following diagnoses:**

**3.1.1.1 Depression**

**OR**

**3.1.1.2 Narcolepsy**

**OR**

**3.1.1.3 Other hypersomnia of central origin**

**OR**

**3.1.1.4 Autism Spectrum Disorder**

**OR**

**3.1.1.5 Mental fatigue secondary to traumatic brain injury (e.g., post-concussion syndrome)**

**OR**

**3.1.1.6 Fatigue associated with medical illness in patients in palliative or end of life care**

**OR**

**3.1.1.7 Fatigue associated with multiple sclerosis**

**OR**

**3.1.1.8 BOTH of the following:**

**3.1.1.8.1** The use of this drug is supported by information from ONE of the following appropriate compendia:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopoeia-National Formulary (USP-NF)

**AND**

**3.1.1.8.2** The drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plans' program

**AND**

**3.1.2 ONE of the following:**

**3.1.2.1** Failure to ALL of the following as confirmed by claims history or submission of medical records^:

- Amphetamine/dextroamphetamine salts extended-release (generic Adderall XR)
- Methylphenidate extended-release tablet or capsule (e.g., generic Concerta or Metadate CD)
- Dexmethylphenidate ER capsule (generic Focalin XR)

**OR**

**3.1.2.2** History of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance)^:

- Amphetamine/dextroamphetamine salts extended-release (generic Adderall XR)
- Methylphenidate extended-release tablet or capsule (e.g., generic Concerta or Metadate CD)
- Dexmethylphenidate ER capsule (generic Focalin XR)

**OR**

**3.1.2.3** History of or potential for a substance abuse disorder

**AND**

**3.1.3** If the request is for BRAND Vyvanse capsules or BRAND Vyvanse chewable tablets, ONE of the following<sup>^\*</sup>:

**3.1.3.1** The multi-source brand is being requested because of an adverse reaction, allergy, or sensitivity to a generic equivalent (specify the adverse reaction, allergy or sensitivity)

**OR**

**3.1.3.2** The multi-source brand is being requested due to a therapeutic failure with the generic equivalent, as documented by submission of medical records

**OR**

**3.1.3.3** The multi-source brand is being requested because transition to a generic equivalent could result in destabilization of the patient

**OR**

**3.1.3.4** Special clinical circumstances exist that preclude the use of a generic version of the multi-source brand medication for the patient (document special clinical circumstances)

**OR**

**3.2** BOTH of the following:

**3.2.1** Diagnosis of Binge Eating Disorder (BED)

**AND**

**3.2.2** If the request is for BRAND Vyvanse capsules or BRAND Vyvanse chewable tablets, ONE of the following<sup>^\*\*</sup>:

**3.2.2.1** The multi-source brand is being requested because of an adverse reaction, allergy, or sensitivity to a generic equivalent (specify the adverse reaction, allergy or sensitivity)

**OR**

**3.2.2.2** The multi-source brand is being requested due to a therapeutic failure with the generic equivalent, as documented by submission of medical records

**OR**

**3.2.2.3** The multi-source brand is being requested because transition to a generic equivalent could result in destabilization of the patient

**OR**

**3.2.2.4** Special clinical circumstances exist that preclude the use of a generic version of the multi-source brand medication for the patient (document special clinical circumstances)

|       |                                                                                                                                                                                                                                                                                                                     |
|-------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Notes | <p>^NJ Psych Panel (any mental health prescriber) is not subject to this criteria.</p> <p>* Generic Vyvanse became available 9/2023. Requests for members currently on brand Vyvanse should be evaluated for use of the GENE RIC, unless the provider provides specific rationale for ongoing use of the brand.</p> |
|-------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

## 2 . Background

| Benefit/Coverage/Program Information           |                          |
|------------------------------------------------|--------------------------|
| Table 1: FDA Approved Minimum Age Table        |                          |
| Product name                                   | FDA Approved Minimum Age |
| All products NOT listed below                  | 6 years of age           |
| Adderall (amphetamine/dextroamphetamine salts) | 3 years of age           |

|                                              |                 |
|----------------------------------------------|-----------------|
| Dexedrine (dextroamphetamine)                | 3 years of age  |
| Evekeo (amphetamine) tablet                  | 3 years of age  |
| Mydayis (mixed amphetamine salts) ER capsule | 13 years of age |
| ProCentra (dextroamphetamine) solution       | 3 years of age  |
| Zenzedi (dextroamphetamine) tablet           | 3 years of age  |

### 3 . Revision History

| Date       | Notes                                                                                                                                                                                                                                                                                                                                                         |
|------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 10/22/2025 | Removed obsolete products, Adhansia XR and Evekeo ODT, as targets. Added Amphetamine ER ODT (MSC M) products as targets. Cleaned up GPI tables and updated product name lists, where applicable. Updated step therapy language in less than FDA approved minimum age criteria section. Updated background table. Minor cosmetic updates throughout guideline. |

Aemcolo



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-249218                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Guideline Name</b> | Aemcolo                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 7/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                      |                     |
|----------------------|---------------------|
| Product Name:Aemcolo |                     |
| Approval Length      | 1 month(s)          |
| Guideline Type       | Prior Authorization |
|                      |                     |

## Approval Criteria

1 - Diagnosis of travelers' diarrhea

**AND**

2 - ONE of the following:

2.1 Failure of ONE of the following confirmed by claims history or submitted medical records:

- Azithromycin (generic Zithromax)
- Ciprofloxacin (generic Cipro)
- Levofloxacin (generic Levaquin)
- Ofloxacin (generic Floxin)

**OR**

2.2 History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication):

- Azithromycin (generic Zithromax)
- Ciprofloxacin (generic Cipro)
- Levofloxacin (generic Levaquin)
- Ofloxacin (generic Floxin)

## 2 . Revision History

| Date      | Notes                                                  |
|-----------|--------------------------------------------------------|
| 4/30/2025 | Combined formularies. No changes to clinical criteria. |



Afinitor, Torpenz



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-354232                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Guideline Name</b> | Afinitor, Torpenz                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Washington (ACUWA, ACUWAAHE, ACUWAC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 9/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                                                                                                            |                       |
|------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name: Brand Afinitor, generic everolimus, Torpenz, Brand Afinitor Disperz, generic everolimus TBSO |                       |
| Diagnosis                                                                                                  | Neuroendocrine tumors |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                       |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1 - ALL of the following:</b></p> <p><b>1.1</b> Diagnosis of ONE of the following:</p> <ul style="list-style-type: none"> <li>• Neuroendocrine tumors of gastrointestinal origin</li> <li>• Neuroendocrine tumors of lung origin</li> <li>• Neuroendocrine tumors of thymic origin</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>1.2</b> ONE of the following:</p> <ul style="list-style-type: none"> <li>• Disease is unresectable</li> <li>• Disease is locally advanced</li> <li>• Disease is metastatic</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>1.3</b> If the request is for Torpenz, ONE of the following:</p> <ul style="list-style-type: none"> <li>• Failure to everolimus (generic Afinitor) as confirmed by claims history or submission of medical records</li> <li>• History of contraindication or intolerance to everolimus (generic Afinitor) (please specify contraindication or intolerance)</li> </ul> <p style="text-align: center;"><b>OR</b></p> <p><b>2 - ALL of the following:</b></p> <p><b>2.1</b> Diagnosis of neuroendocrine tumors of pancreatic origin</p> |                       |

**AND**

**2.2 ONE of the following:**

- Used for the management of recurrent, locoregional advanced and/or metastatic disease
- Used for management to stabilize glucose levels of locoregional insulinoma

**AND**

**2.3 If the request is for Torpenz, ONE of the following:**

- Failure to everolimus (generic Afinitor) as confirmed by claims history or submission of medical records
- History of contraindication or intolerance to everolimus (generic Afinitor) (please specify contraindication or intolerance)

**OR**

**3 - ALL of the following:**

**3.1 Diagnosis of well-differentiated, grade 3 neuroendocrine tumor**

**AND**

**3.2 ONE of the following:**

- Disease is unresectable
- Disease is locally advanced
- Disease is metastatic

**AND**

**3.3 Tumor has favorable biology (e.g., relatively low Ki-67 [**

**AND**

**3.4** If the request is for Torpenz, ONE of the following:

- Failure to everolimus (generic Afinitor) as confirmed by claims history or submission of medical records
- History of contraindication or intolerance to everolimus (generic Afinitor) (please specify contraindication or intolerance)

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                       |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name: Brand Afinitor, generic everolimus, Torpenz, Brand Afinitor Disperz, generic everolimus TBSO                                                                                                                                                                                                                                                                                                                                                                                                   |                       |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Kidney Cancer         |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - ONE of the following:</p> <p><b>1.1</b> BOTH of the following:</p> <ul style="list-style-type: none"> <li>• Diagnosis of kidney cancer</li> <li>• Disease is relapsed or stage IV</li> </ul> <p style="text-align: center;"><b>OR</b></p> <p><b>1.2</b> Diagnosis of tuberous sclerosis complex (TSC)-associated renal cell carcinoma</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - If the request is for Torpenz, ONE of the following:</p> |                       |

- Failure to everolimus (generic Afinitor) as confirmed by claims history or submission of medical records
- History of contraindication or intolerance to everolimus (generic Afinitor) (please specify contraindication or intolerance)

Product Name: Brand Afinitor, generic everolimus, Torpenz, Brand Afinitor Disperz, generic everolimus TBSO

|           |                               |
|-----------|-------------------------------|
| Diagnosis | Central Nervous System Cancer |
|-----------|-------------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

### Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of subependymal giant cell astrocytoma (SEGA)

**AND**

1.2 Used as adjuvant treatment

**AND**

1.3 If the request is for Torpenz, ONE of the following:

- Failure to everolimus (generic Afinitor) as confirmed by claims history or submission of medical records
- History of contraindication or intolerance to everolimus (generic Afinitor) (please specify contraindication or intolerance)

**OR**

2 - ALL of the following:

**2.1** Diagnosis of meningioma

**AND**

**2.2** Disease is recurrent or progressive

**AND**

**2.3** Surgery and/or radiation is not possible

**AND**

**2.4** ONE of the following:

- Used in combination with bevacizumab (Avastin, Mvasi, etc.)
- Used in combination with octreotide acetate LAR

**AND**

**2.5** If the request is for Torpenz, ONE of the following:

- Failure to everolimus (generic Afinitor) as confirmed by claims history or submission of medical records
- History of contraindication or intolerance to everolimus (generic Afinitor) (please specify contraindication or intolerance)

|                                                                                                            |                                                              |
|------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------|
| Product Name: Brand Afinitor, generic everolimus, Torpenz, Brand Afinitor Disperz, generic everolimus TBSO |                                                              |
| Diagnosis                                                                                                  | Waldenströms Macroglobulinemia or Lymphoplasmacytic Lymphoma |
| Approval Length                                                                                            | 12 month(s)                                                  |
| Therapy Stage                                                                                              | Initial Authorization                                        |
| Guideline Type                                                                                             | Prior Authorization                                          |

### Approval Criteria

1 - Diagnosis of one of the following:

- Waldenströms macroglobulinemia
- Lymphoplasmacytic lymphoma

**AND**

2 - One of the following:

- Disease is non-responsive to primary treatment
- Disease is progressive
- Disease has relapsed

**AND**

3 - If the request is for Torpenz, ONE of the following:

- Failure to everolimus (generic Afinitor) as confirmed by claims history or submission of medical records
- History of contraindication or intolerance to everolimus (generic Afinitor) (please specify contraindication or intolerance)

Product Name: Brand Afinitor, generic everolimus, Torpenz, Brand Afinitor Disperz, generic everolimus TBSO

|                 |                       |
|-----------------|-----------------------|
| Diagnosis       | Breast Cancer         |
| Approval Length | 12 month(s)           |
| Therapy Stage   | Initial Authorization |
| Guideline Type  | Prior Authorization   |

### Approval Criteria

1 - Diagnosis of breast cancer

**AND**

**2 - ONE of the following:**

- Disease is recurrent
- Disease is metastatic

**AND**

**3 - ONE of the following:**

- Disease is hormone receptor positive (HR+) [i.e., estrogen-receptor-positive (ER+) or progesterone-receptor-positive (PR+)]
- Breast cancer is considered inflammatory

**AND**

**4 - Disease is human epidermal growth factor receptor 2 (HER2)-negative**

**AND**

**5 - One of the following:**

**5.1 Patient is a postmenopausal woman**

**OR**

**5.2 BOTH of the following:**

- Patient is a premenopausal woman
- Patient is being treated with ovarian ablation/suppression

**OR**

**5.3 Patient is male**



**AND**

**6** - Used in combination with ONE of the following:

- Exemestane if progressed within 12 months or on a non-steroidal aromatase inhibitor [e.g., Arimidex (anastrozole), Femara (letrozole)]
- Fulvestrant
- Tamoxifen

**AND**

**7** - If the request is for Torpenz, ONE of the following:

- Failure to everolimus (generic Afinitor) as confirmed by claims history or submission of medical records
- History of contraindication or intolerance to everolimus (generic Afinitor) (please specify contraindication or intolerance)

Product Name: Brand Afinitor, generic everolimus, Torpenz, Brand Afinitor Disperz, generic everolimus TBSO

|                 |                       |
|-----------------|-----------------------|
| Diagnosis       | Hodgkin Lymphoma      |
| Approval Length | 12 month(s)           |
| Therapy Stage   | Initial Authorization |
| Guideline Type  | Prior Authorization   |

**Approval Criteria**

**1** - Diagnosis of classic Hodgkin lymphoma

**AND**

**2** - Disease is relapsed or refractory

**AND**

**3** - Patient is not a candidate for autologous stem cell rescue/high-dose therapy (ASCR/HDT)

**AND**

**4** - If the request is for Torpenz, ONE of the following:

- Failure to everolimus (generic Afinitor) as confirmed by claims history or submission of medical records
- History of contraindication or intolerance to everolimus (generic Afinitor) (please specify contraindication or intolerance)

Product Name: Brand Afinitor, generic everolimus, Torpenz, Brand Afinitor Disperz, generic everolimus TBSO

|                 |                       |
|-----------------|-----------------------|
| Diagnosis       | Soft Tissue Sarcoma   |
| Approval Length | 12 month(s)           |
| Therapy Stage   | Initial Authorization |
| Guideline Type  | Prior Authorization   |

### Approval Criteria

**1** - Diagnosis of ONE of the following soft tissue sarcoma subtypes:

- Locally advanced unresectable or metastatic malignant perivascular epithelioid cell tumor (PEComa)
- Recurrent angiomyolipoma
- Lymphangioleiomyomatosis

**AND**

**2** - If the request is for Torpenz, ONE of the following:

- Failure to everolimus (generic Afinitor) as confirmed by claims history or submission of medical records
- History of contraindication or intolerance to everolimus (generic Afinitor) (please specify contraindication or intolerance)

Product Name: Brand Afinitor, generic everolimus, Torpenz, Brand Afinitor Disperz, generic everolimus TBSO

|                 |                                |
|-----------------|--------------------------------|
| Diagnosis       | Thymomas and Thymic Carcinomas |
| Approval Length | 12 month(s)                    |
| Therapy Stage   | Initial Authorization          |
| Guideline Type  | Prior Authorization            |

### Approval Criteria

1 - One of the following:

- Diagnosis of thymic carcinoma
- Diagnosis of thymoma

**AND**

2 - ONE of the following:

- First-line therapy as a single agent for those who cannot tolerate first-line combination regimens
- Second-line therapy as a single agent

**AND**

3 - If the request is for Torpenz, ONE of the following:

- Failure to everolimus (generic Afinitor) as confirmed by claims history or submission of medical records
- History of contraindication or intolerance to everolimus (generic Afinitor) (please specify contraindication or intolerance)

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                       |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name: Brand Afinitor, generic everolimus, Torpenz, Brand Afinitor Disperz, generic everolimus TBSO                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                       |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Thyroid Carcinoma     |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1 - Diagnosis of ONE of the following:</b></p> <ul style="list-style-type: none"> <li>• Follicular carcinoma</li> <li>• Oncocytic carcinoma</li> <li>• Papillary carcinoma</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>2 - ONE of the following:</b></p> <ul style="list-style-type: none"> <li>• Unresectable locoregional recurrent disease</li> <li>• Persistent disease</li> <li>• Metastatic disease</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>3 - ONE of the following:</b></p> <ul style="list-style-type: none"> <li>• Patient has symptomatic disease</li> <li>• Patient has progressive disease</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>4 - If the request is for Torpenz, ONE of the following:</b></p> <ul style="list-style-type: none"> <li>• Failure to everolimus (generic Afinitor) as confirmed by claims history or submission of medical records</li> </ul> |                       |

- History of contraindication or intolerance to everolimus (generic Afinitor) (please specify contraindication or intolerance)

Product Name: Brand Afinitor, generic everolimus, Torpenz, Brand Afinitor Disperz, generic everolimus TBSO

|                 |                       |
|-----------------|-----------------------|
| Diagnosis       | Uterine Neoplasm      |
| Approval Length | 12 month(s)           |
| Therapy Stage   | Initial Authorization |
| Guideline Type  | Prior Authorization   |

### Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of endometrial carcinoma

**AND**

1.2 Used in combination with letrozole

**AND**

1.3 If the request is for Torpenz, ONE of the following:

- Failure to everolimus (generic Afinitor) as confirmed by claims history or submission of medical records
- History of contraindication or intolerance to everolimus (generic Afinitor) (please specify contraindication or intolerance)

**OR**

2 - ALL of the following:

2.1 Diagnosis of Uterine Sarcoma

**AND**

**2.2** Disease is perivascular epithelioid cell tumor (PEComa)

**AND**

**2.3** Used as second-line or subsequent therapy

**AND**

**2.4** If the request is for Torpenz, ONE of the following:

- Failure to everolimus (generic Afinitor) as confirmed by claims history or submission of medical records
- History of contraindication or intolerance to everolimus (generic Afinitor) (please specify contraindication or intolerance)

Product Name: Brand Afinitor, generic everolimus, Torpenz, Brand Afinitor Disperz, generic everolimus TBSO

|                 |                                                              |
|-----------------|--------------------------------------------------------------|
| Diagnosis       | Tuberous Sclerosis Complex associated Partial-Onset Seizures |
| Approval Length | 12 month(s)                                                  |
| Therapy Stage   | Initial Authorization                                        |
| Guideline Type  | Prior Authorization                                          |

**Approval Criteria**

**1** - Diagnosis of tuberous sclerosis complex associated partial-onset seizures

**AND**

**2** - Used as adjunctive therapy

**AND**

**3** - If the request is for Torpenz, ONE of the following:

- Failure to everolimus (generic Afinitor) as confirmed by claims history or submission of medical records
- History of contraindication or intolerance to everolimus (generic Afinitor) (please specify contraindication or intolerance)

Product Name: Brand Afinitor, generic everolimus, Torpenz, Brand Afinitor Disperz, generic everolimus TBSO

|           |                            |
|-----------|----------------------------|
| Diagnosis | Bone Cancer - Osteosarcoma |
|-----------|----------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

### Approval Criteria

**1** - Diagnosis of osteosarcoma

**AND**

**2** - Disease is ONE of the following:

- Relapsed/Refractory
- Metastatic

**AND**

**3** - Used as second-line therapy

**AND**

**4** - Used in combination with Nexavar (sorafenib)

**AND**

**5** - If the request is for Torpenz, ONE of the following:

- Failure to everolimus (generic Afinitor) as confirmed by claims history or submission of medical records
- History of contraindication or intolerance to everolimus (generic Afinitor) (please specify contraindication or intolerance)

Product Name: Brand Afinitor, generic everolimus, Torpenz, Brand Afinitor Disperz, generic everolimus TBSO

|                 |                       |
|-----------------|-----------------------|
| Diagnosis       | Histiocytic Neoplasms |
| Approval Length | 12 month(s)           |
| Therapy Stage   | Initial Authorization |
| Guideline Type  | Prior Authorization   |

### Approval Criteria

**1** - Diagnosis of ONE of the following

- Rosai-Dorfman Disease
- Langerhans Cell Histiocytosis
- Erdheim-Chester Disease

**AND**

**2** - Presence of phosphatidylinositol-4,5-bisphosphate 3-kinase catalytic subunit alpha (PIK3CA) mutation

**AND**

**3** - If the request is for Torpenz, ONE of the following:



- Failure to everolimus (generic Afinitor) as confirmed by claims history or submission of medical records
- History of contraindication or intolerance to everolimus (generic Afinitor) (please specify contraindication or intolerance)

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                       |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|
| Product Name: Brand Afinitor, generic everolimus, Torpenz, Brand Afinitor Disperz, generic everolimus TBSO                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                       |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Gastrointestinal Stromal Tumor (GIST) |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 12 month(s)                           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Initial Authorization                 |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Prior Authorization                   |
| <p><b>Approval Criteria</b></p> <p><b>1 - Diagnosis of Gastrointestinal Stromal Tumor (GIST)</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>2 - Disease is one of the following:</b></p> <ul style="list-style-type: none"> <li>• Unresectable primary</li> <li>• Recurrent/Metastatic</li> <li>• Gross residual (R2 resection)</li> <li>• Tumor rupture</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>3 - Disease has progressed after single agent therapy with ALL of the following:</b></p> <ul style="list-style-type: none"> <li>• imatinib (generic Gleevec)</li> <li>• sunitinib (generic Sutent)</li> <li>• Stivarga (regorafenib)</li> <li>• Qinlock (ripretinib)</li> </ul> |                                       |

**AND**

**4** - Used in combination with ONE of the following:

- imatinib (generic Gleevec)
- sunitinib (generic Sutent)
- Stivarga (regorafenib)

**AND**

**5** - If the request is for Torpenz, ONE of the following:

- Failure to everolimus (generic Afinitor) as confirmed by claims history or submission of medical records
- History of contraindication or intolerance to everolimus (generic Afinitor) (please specify contraindication or intolerance)

Product Name: Brand Afinitor, generic everolimus, Torpenz, Brand Afinitor Disperz, generic everolimus TBSO

|           |                                                                                                                                                                                                                                                                                                                                                                                                                       |
|-----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Diagnosis | Neuroendocrine Tumors, Kidney Cancer, Central Nervous System Cancer, Waldenström's Macroglobulinemia or Lymphoplasmacytic Lymphoma, Breast Cancer, Hodgkin Lymphoma, Soft Tissue Sarcoma, Thymomas and Thymic Carcinomas, Thyroid Carcinoma, Uterine Neoplasm, Tuberous Sclerosis Complex associated Partial-Onset Seizures, Bone Cancer - Osteosarcoma, Histiocytic Neoplasms, Gastrointestinal Stromal Tumor (GIST) |
|-----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                 |
|---------------|-----------------|
| Therapy Stage | Reauthorization |
|---------------|-----------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

**1** - Patient does not show evidence of progressive disease while on therapy

Product Name: Brand Afinitor, generic everolimus, Torpenz, Brand Afinitor Disperz, generic everolimus TBSO

|                                                                                                                                             |                           |
|---------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Diagnosis                                                                                                                                   | NCCN Recommended Regimens |
| Approval Length                                                                                                                             | 12 month(s)               |
| Therapy Stage                                                                                                                               | Initial Authorization     |
| Guideline Type                                                                                                                              | Prior Authorization       |
| <b>Approval Criteria</b><br><br><b>1</b> - Use supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium |                           |

|                                                                                                           |                           |
|-----------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Brand Afinitor, generic everolimus, Torpenz, Brand Afinitor Disperz, generic everolimus TBSO |                           |
| Diagnosis                                                                                                 | NCCN Recommended Regimens |
| Approval Length                                                                                           | 12 month(s)               |
| Therapy Stage                                                                                             | Reauthorization           |
| Guideline Type                                                                                            | Prior Authorization       |
| <b>Approval Criteria</b><br><br><b>1</b> - Documentation of positive clinical response to therapy         |                           |

## 2 . Revision History

| Date     | Notes                         |
|----------|-------------------------------|
| 8/4/2025 | Updated formularies to add IN |

Afrezza



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-267200                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Guideline Name</b> | Afrezza                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 7/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                      |                       |
|----------------------|-----------------------|
| Product Name:Afrezza |                       |
| Approval Length      | 12 month(s)           |
| Therapy Stage        | Initial Authorization |
| Guideline Type       | Prior Authorization   |

### **Approval Criteria**

**1** - One of the following:

**1.1** Diagnosis of type 1 diabetes mellitus and used in combination with a basal insulin or continuous insulin pump

**OR**

**1.2** Diagnosis of type 2 diabetes mellitus

**AND**

**2** - Patient is unable to self-inject medications (e.g. Humalog, Lantus, Levemir) due to ONE of the following:

- Physical impairment
- Visual impairment
- Lipohypertrophy
- Documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-5 for specific phobia diagnostic criteria)

**AND**

**3** - Forced Expiratory Volume (FEV1) within the last 60 days is greater than or equal to 70% of expected normal as determined by the physician

**AND**

**4** - Afrezza will not be approved in patients with ONE of the following:

- Who smoke cigarettes
- Who recently quit smoking (within the past 6 months)
- With chronic lung disease (e.g. asthma, chronic obstructive pulmonary disease)

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                     |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name: Afrezza                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                     |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 12 month(s)         |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Repeat pulmonary function test confirms that patient has NOT experienced a decline of 20% or more in Forced Expiratory Volume (FEV1)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Patient continues to be unable to self-inject short-acting insulin due to ONE of the following:</p> <ul style="list-style-type: none"> <li>Physical impairment</li> <li>Visual impairment</li> <li>Lipohypertrophy</li> <li>Documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-5 for specific phobia diagnostic criteria)</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Patient continues to not smoke cigarettes</p> |                     |

## 2 . Revision History

| Date      | Notes               |
|-----------|---------------------|
| 5/15/2025 | Updated formularies |

Agamree



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-155757                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Guideline Name</b> | Agamree                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 10/1/2024 |
|-----------------|-----------|

## 1 . Criteria

|                      |                             |
|----------------------|-----------------------------|
| Product Name:Agamree |                             |
| Diagnosis            | Duchenne Muscular Dystrophy |
| Guideline Type       | Prior Authorization         |
| Approval Criteria    |                             |

**1** - Published clinical evidence shows Agamree is likely to produce equivalent therapeutic results as other available corticosteroids (e.g., prednisone); therefore, Agamree is not medically necessary for treatment of Duchenne muscular dystrophy

|       |                                                                                                                                                                                            |
|-------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Notes | All requests for authorization will be denied by OptumRx and must be submitted through the appeals process to the UnitedHealthcare Community Plan Pharmacy Appeals team for consideration. |
|-------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

## 2 . Revision History

| Date      | Notes         |
|-----------|---------------|
| 9/23/2024 | New Guideline |



Akeega



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-164692                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Guideline Name</b> | Akeega                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Washington (ACUWA, ACUWAAHE, ACUWAC)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 2/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                     |                 |
|---------------------|-----------------|
| Product Name:Akeega |                 |
| Diagnosis           | Prostate Cancer |
| Approval Length     | 12 month(s)     |

|                                                                                                                                                                                                                                                                                                                                               |                       |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                                                                                                                                                                                                                                                                                 | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                | Prior Authorization   |
| <b>Approval Criteria</b><br><br><b>1</b> - Diagnosis of metastatic castration-resistant prostate cancer (mCRPC)<br><br><p style="text-align: center;"><b>AND</b></p> <b>2</b> - Deleterious or suspected deleterious BRCA-mutated (BRCAm)<br><br><p style="text-align: center;"><b>AND</b></p> <b>3</b> - Used in combination with prednisone |                       |

|                                                                                                                          |                     |
|--------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Akeega                                                                                                      |                     |
| Diagnosis                                                                                                                | Prostate Cancer     |
| Approval Length                                                                                                          | 12 month(s)         |
| Therapy Stage                                                                                                            | Reauthorization     |
| Guideline Type                                                                                                           | Prior Authorization |
| <b>Approval Criteria</b><br><br><b>1</b> - Patient does not show evidence of progressive disease while on Akeega therapy |                     |

|                     |                           |
|---------------------|---------------------------|
| Product Name:Akeega |                           |
| Diagnosis           | NCCN Recommended Regimens |
| Approval Length     | 12 month(s)               |
| Therapy Stage       | Initial Authorization     |
| Guideline Type      | Prior Authorization       |

**Approval Criteria**

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

|                                                                                                          |                           |
|----------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Akeega                                                                                      |                           |
| Diagnosis                                                                                                | NCCN Recommended Regimens |
| Approval Length                                                                                          | 12 month(s)               |
| Therapy Stage                                                                                            | Reauthorization           |
| Guideline Type                                                                                           | Prior Authorization       |
| <p><b>Approval Criteria</b></p> <p>1 - Documentation of positive clinical response to Akeega therapy</p> |                           |

## 2 . Revision History

| Date     | Notes                                               |
|----------|-----------------------------------------------------|
| 2/4/2025 | Added IN formulary. No change to clinical criteria. |

Alecensa



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-354240                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Guideline Name</b> | Alecensa                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 9/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                       |                                    |
|-----------------------|------------------------------------|
| Product Name:Alecensa |                                    |
| Diagnosis             | Non-Small Cell Lung Cancer (NSCLC) |
| Approval Length       | 12 month(s)                        |
| Therapy Stage         | Initial Authorization              |

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Prior Authorization |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of non-small cell lung cancer (NSCLC)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Disease is anaplastic lymphoma kinase (ALK)-positive</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - One of the following:</p> <p><b>3.1</b> Disease is one of the following:</p> <ul style="list-style-type: none"> <li>• Recurrent</li> <li>• Advanced</li> <li>• Metastatic</li> </ul> <p style="text-align: center;"><b>OR</b></p> <p><b>3.2</b> Used as adjuvant treatment following tumor resection</p> |                     |

|                                                                                                    |                       |
|----------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Alecensa                                                                              |                       |
| Diagnosis                                                                                          | Histiocytic Neoplasms |
| Approval Length                                                                                    | 12 month(s)           |
| Therapy Stage                                                                                      | Initial Authorization |
| Guideline Type                                                                                     | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of symptomatic Erdheim-Chester Disease</p> |                       |

**AND**

**2** - Used as targeted therapy anaplastic lymphoma kinase (ALK)-fusion

**AND**

**3** - Disease is ONE of the following:

- Relapsed
- Refractory

|                                                                                                                                                                                                                                                                                                                                                                                  |                       |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Alecensa                                                                                                                                                                                                                                                                                                                                                            |                       |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                        | T-Cell Lymphomas      |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                  | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                    | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                   | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of anaplastic large cell lymphoma (ALCL)</p> <p><b>AND</b></p> <p><b>2</b> - Used as initial palliative intent therapy or second-line and subsequent therapy</p> <p><b>AND</b></p> <p><b>3</b> - Disease is ONE of the following:</p> <ul style="list-style-type: none"> <li>• Relapsed</li> <li>• Refractory</li> </ul> |                       |

**AND**

**4 - Anaplastic lymphoma kinase (ALK)-positive**

Product Name:Alecensa

|           |                  |
|-----------|------------------|
| Diagnosis | B-Cell Lymphomas |
|-----------|------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

**1 - Diagnosis of large B-Cell lymphoma**

**AND**

**2 - Disease is ONE of the following:**

- Relapsed
- Refractory

**AND**

**3 - Anaplastic lymphoma kinase (ALK)-positive**

Product Name:Alecensa

|           |                                      |
|-----------|--------------------------------------|
| Diagnosis | Central Nervous System (CNS) Cancers |
|-----------|--------------------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

**1** - Diagnosis of ONE of the following:

- Metastatic brain cancer from NSCLC
- Pediatric diffuse high-grade glioma

**AND**

**2** - Tumor is anaplastic lymphoma kinase (ALK)-positive

|                                                                                                                                                                                                        |                                       |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|
| Product Name:Alecensa                                                                                                                                                                                  |                                       |
| Diagnosis                                                                                                                                                                                              | Soft Tissue Sarcoma/Uterine Neoplasms |
| Approval Length                                                                                                                                                                                        | 12 month(s)                           |
| Therapy Stage                                                                                                                                                                                          | Initial Authorization                 |
| Guideline Type                                                                                                                                                                                         | Prior Authorization                   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of inflammatory myofibroblastic tumor (IMT)</p> <p><b>AND</b></p> <p><b>2</b> - Presence of anaplastic lymphoma kinase (ALK) translocation</p> |                                       |

|                       |                                                                                                                                                                            |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Product Name:Alecensa |                                                                                                                                                                            |
| Diagnosis             | Non-Small Cell Lung Cancer (NSCLC), Histiocytic Neoplasms, T-Cell Lymphomas, B-Cell Lymphomas, Central Nervous System (CNS) Cancers, Soft Tissue Sarcoma/Uterine Neoplasms |
| Approval Length       | 12 month(s)                                                                                                                                                                |
| Therapy Stage         | Reauthorization                                                                                                                                                            |
| Guideline Type        | Prior Authorization                                                                                                                                                        |



**Approval Criteria**

1 - Patient does not show evidence of progressive disease while on Alecensa therapy

Product Name:Alecensa

|           |                           |
|-----------|---------------------------|
| Diagnosis | NCCN Recommended Regimens |
|-----------|---------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Alecensa

|           |                           |
|-----------|---------------------------|
| Diagnosis | NCCN Recommended Regimens |
|-----------|---------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                 |
|---------------|-----------------|
| Therapy Stage | Reauthorization |
|---------------|-----------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

1 - Documentation of positive clinical response to Alecensa therapy

## 2 . Revision History

| Date     | Notes                                                              |
|----------|--------------------------------------------------------------------|
| 8/4/2025 | Added pediatric diffuse high-grade gliomas to CNS cancers criteria |



Alfa Interferons



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-158354                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Guideline Name</b> | Alfa Interferons                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 1/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                      |                     |
|----------------------|---------------------|
| Product Name:Pegasys |                     |
| Diagnosis            | Chronic Hepatitis B |
| Approval Length      | 48 Week(s)          |
| Guideline Type       | Prior Authorization |
|                      |                     |

**Approval Criteria**

1 - Diagnosis of chronic hepatitis B infection

**AND**

2 - Patient does not have decompensated liver disease (defined as Child-Pugh Class B or C)

Product Name:Pegasys

|           |                     |
|-----------|---------------------|
| Diagnosis | Chronic Hepatitis C |
|-----------|---------------------|

|                 |            |
|-----------------|------------|
| Approval Length | 48 Week(s) |
|-----------------|------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

1 - Diagnosis of chronic hepatitis C infection

**AND**

2 - Patient does not have decompensated liver disease (defined as Child-Pugh Class B or C)

**AND**

3 - Will be used as part of a combination antiviral treatment regimen

Product Name:Pegasys

|           |                                |
|-----------|--------------------------------|
| Diagnosis | Diagnoses Other Than Hepatitis |
|-----------|--------------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

1 - Patient has ONE of the following diagnoses:

- Chronic myeloid leukemia (CML)
- Hairy cell leukemia
- Erdheim-Chester disease (ECD)
- Myeloproliferative neoplasms (MPNs) such as essential thrombocythemia (ET), polycythemia vera (PV), or myelofibrosis (MF)
- Mycosis fungoides/Sezary syndrome
- Primary cutaneous CD30+ T-cell lymphoproliferative disorders
- Systemic mastocytosis
- Adult T-cell leukemia/lymphoma

Product Name:Pegasys

|                 |                           |
|-----------------|---------------------------|
| Diagnosis       | NCCN Recommended Regimens |
| Approval Length | 12 month(s)               |
| Therapy Stage   | Initial Authorization     |
| Guideline Type  | Prior Authorization       |

#### Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Pegasys

|                 |                           |
|-----------------|---------------------------|
| Diagnosis       | NCCN Recommended Regimens |
| Approval Length | 12 month(s)               |
| Therapy Stage   | Reauthorization           |
| Guideline Type  | Prior Authorization       |

#### Approval Criteria

1 - Documentation of positive clinical response to Pegasys therapy

## 2 . Revision History

| Date       | Notes            |
|------------|------------------|
| 10/31/2024 | Removed Intron A |

Alhemo



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-429196                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Guideline Name</b> | Alhemo                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 11/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                     |                              |
|---------------------|------------------------------|
| Product Name:Alhemo |                              |
| Diagnosis           | Hemophilia A With Inhibitors |
| Approval Length     | 12 month(s)                  |
| Therapy Stage       | Initial Authorization        |
| Guideline Type      | Prior Authorization          |

**Approval Criteria**

1 - BOTH of the following:

1.1 Diagnosis of hemophilia A

**AND**

1.2 Patient has developed high-titer factor VIII inhibitors (i.e., patient has developed factor VIII inhibitors greater than or equal to 5 Bethesda units [BU])

**AND**

2 - Patient is 12 years of age or older

**AND**

3 - Prescribed for the prevention of bleeding episodes (i.e., routine prophylaxis)

|                                                                                                        |                                 |
|--------------------------------------------------------------------------------------------------------|---------------------------------|
| Product Name:Alhemo                                                                                    |                                 |
| Diagnosis                                                                                              | Hemophilia A Without Inhibitors |
| Approval Length                                                                                        | 12 month(s)                     |
| Therapy Stage                                                                                          | Initial Authorization           |
| Guideline Type                                                                                         | Prior Authorization             |
| <p><b>Approval Criteria</b></p> <p>1 - BOTH of the following:</p> <p>1.1 Diagnosis of hemophilia A</p> |                                 |



**AND**

**1.2** Patient has NOT developed high-titer factor VIII inhibitors (i.e., patient has NOT developed factor VIII inhibitors greater than or equal to 5 Bethesda units [BU])

**AND**

**2** - Patient is 12 years of age or older

**AND**

**3** - Alhemo is prescribed for the prevention of bleeding episodes (i.e., routine prophylaxis)

|                                                                                                                                                                                                                                                                                                                                    |                              |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|
| Product Name:Alhemo                                                                                                                                                                                                                                                                                                                |                              |
| Diagnosis                                                                                                                                                                                                                                                                                                                          | Hemophilia B With Inhibitors |
| Approval Length                                                                                                                                                                                                                                                                                                                    | 12 month(s)                  |
| Therapy Stage                                                                                                                                                                                                                                                                                                                      | Initial Authorization        |
| Guideline Type                                                                                                                                                                                                                                                                                                                     | Prior Authorization          |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - BOTH of the following:</p> <p><b>1.1</b> Diagnosis of hemophilia B</p> <p><b>AND</b></p> <p><b>1.2</b> Patient has developed high-titer factor IX inhibitors (i.e., patient has developed factor IX inhibitors greater than or equal to 5 Bethesda units [BU])</p> <p><b>AND</b></p> |                              |

**2** - Patient is 12 years of age or older

**AND**

**3** - Prescribed for the prevention of bleeding episodes (i.e., routine prophylaxis)

Product Name:Alhemo

|           |                                 |
|-----------|---------------------------------|
| Diagnosis | Hemophilia B Without Inhibitors |
|-----------|---------------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

### Approval Criteria

**1** - BOTH of the following:

**1.1** Diagnosis of hemophilia B

**AND**

**1.2** Patient has NOT developed high-titer factor IX inhibitors (i.e., patient has NOT developed factor IX inhibitors greater than or equal to 5 Bethesda units [BU])

**AND**

**2** - Patient is 12 years of age or older

**AND**

**3** - Alhemo is prescribed for the prevention of bleeding episodes (i.e., routine prophylaxis)

Product Name:Alhemo

|                                                                                                          |                                                                                                                              |
|----------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------|
| Diagnosis                                                                                                | Hemophilia A With Inhibitors, Hemophilia A Without Inhibitors, Hemophilia B With Inhibitors, Hemophilia B Without Inhibitors |
| Approval Length                                                                                          | 12 month(s)                                                                                                                  |
| Therapy Stage                                                                                            | Reauthorization                                                                                                              |
| Guideline Type                                                                                           | Prior Authorization                                                                                                          |
| <b>Approval Criteria</b><br><br><b>1</b> - Documentation of positive clinical response to Alhemo therapy |                                                                                                                              |

## 2 . Revision History

| Date       | Notes                                                                                                                                                                                                 |
|------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 10/24/2025 | Removed MI from markets in scope. Added new criteria for hemophili a A and B without inhibitors. Updated high titer factor criterion in initial auth sections for hemophilia A and B with inhibitors. |

Alinia



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-375606                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Guideline Name</b> | Alinia                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 10/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                                                 |                                    |
|-------------------------------------------------|------------------------------------|
| Product Name:generic nitazoxanide, Brand Alinia |                                    |
| Diagnosis                                       | Diarrhea caused by Giardia lamblia |
| Approval Length                                 | 1 month(s)                         |
| Guideline Type                                  | Prior Authorization                |

**Approval Criteria**

1 - Diagnosis of giardiasis

**AND**

2 - ONE of the following:

2.1 Failure to metronidazole, as confirmed by claims history or submission of medical records

**OR**

2.2 History of contraindication or intolerance to metronidazole (please specify contraindication or intolerance)

|                                                                           |                                           |
|---------------------------------------------------------------------------|-------------------------------------------|
| Product Name:generic nitazoxanide, Brand Alinia                           |                                           |
| Diagnosis                                                                 | Diarrhea caused by Cryptosporidium parvum |
| Approval Length                                                           | 12 month(s)                               |
| Guideline Type                                                            | Prior Authorization                       |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of cryptosporidiosis</p> |                                           |

## 2 . Revision History

| Date      | Notes               |
|-----------|---------------------|
| 8/27/2025 | Added NM formulary. |

Alunbrig



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-157619                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Guideline Name</b> | Alunbrig                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 12/1/2024 |
|-----------------|-----------|

## 1 . Criteria

|                       |                                    |
|-----------------------|------------------------------------|
| Product Name:Alunbrig |                                    |
| Diagnosis             | Non-Small Cell Lung Cancer (NSCLC) |
| Approval Length       | 12 month(s)                        |
| Therapy Stage         | Initial Authorization              |
| Guideline Type        | Prior Authorization                |

**Approval Criteria**

**1** - Diagnosis of non-small cell lung cancer (NSCLC)

**AND**

**2** - Disease is ONE of the following:

- Metastatic
- Recurrent
- Advanced

**AND**

**3** - Tumor is anaplastic lymphoma kinase (ALK)-positive

|                                                                                                                                                                                                        |                                       |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|
| Product Name:Alunbrig                                                                                                                                                                                  |                                       |
| Diagnosis                                                                                                                                                                                              | Soft Tissue Sarcoma/Uterine Neoplasms |
| Approval Length                                                                                                                                                                                        | 12 month(s)                           |
| Therapy Stage                                                                                                                                                                                          | Initial Authorization                 |
| Guideline Type                                                                                                                                                                                         | Prior Authorization                   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of inflammatory myofibroblastic tumor (IMT)</p> <p><b>AND</b></p> <p><b>2</b> - Presence of ALK (anaplastic lymphoma kinase) translocation</p> |                                       |

|                       |
|-----------------------|
| Product Name:Alunbrig |
|-----------------------|

|                                                                                                                                                                                                                                                                                                                                                                                                    |                       |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                          | Histiocytic Neoplasms |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                    | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                      | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                     | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of symptomatic Erdheim-Chester Disease</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Used as targeted therapy (anaplastic lymphoma kinase) ALK-fusion</p> <p style="text-align: center;"><b>AND</b></p> <p>3 - Disease is ONE of the following:</p> <ul style="list-style-type: none"> <li>• Relapsed</li> <li>• Refractory</li> </ul> |                       |

|                                                                                                                                          |                                      |
|------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|
| Product Name:Alunbrig                                                                                                                    |                                      |
| Diagnosis                                                                                                                                | Central Nervous System (CNS) Cancers |
| Approval Length                                                                                                                          | 12 month(s)                          |
| Therapy Stage                                                                                                                            | Initial Authorization                |
| Guideline Type                                                                                                                           | Prior Authorization                  |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of metastatic brain cancer from NSCLC</p> <p style="text-align: center;"><b>AND</b></p> |                                      |



**2 - Tumor is anaplastic lymphoma kinase (ALK)-positive**

**Product Name:**Alunbrig

|                 |                                |
|-----------------|--------------------------------|
| Diagnosis       | Anaplastic Large Cell Lymphoma |
| Approval Length | 12 month(s)                    |
| Therapy Stage   | Initial Authorization          |
| Guideline Type  | Prior Authorization            |

**Approval Criteria**

**1 - Diagnosis of anaplastic large cell lymphoma**

**AND**

**2 - Tumor is anaplastic lymphoma kinase (ALK)-positive**

**AND**

**3 - Disease is relapsed or refractory**

**AND**

**4 - Used as palliative intent therapy or second-line and subsequent therapy**

**Product Name:**Alunbrig

|                 |                                                                                                                                                                        |
|-----------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Diagnosis       | Non-Small Cell Lung Cancer (NSCLC), Soft Tissue Sarcoma/Uterine Neoplasms, Histiocytic Neoplasms, Central Nervous System (CNS) Cancers, Anaplastic Large Cell Lymphoma |
| Approval Length | 12 month(s)                                                                                                                                                            |
| Therapy Stage   | Reauthorization                                                                                                                                                        |
| Guideline Type  | Prior Authorization                                                                                                                                                    |

**Approval Criteria**

1 - Patient does not show evidence of progressive disease while on Alunbrig therapy

|                                                                                                                                                |                                                                   |
|------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| Product Name:Alunbrig                                                                                                                          |                                                                   |
| Diagnosis                                                                                                                                      | National Comprehensive Cancer Network (NCCN) Recommended Regimens |
| Approval Length                                                                                                                                | 12 month(s)                                                       |
| Therapy Stage                                                                                                                                  | Initial Authorization                                             |
| Guideline Type                                                                                                                                 | Prior Authorization                                               |
| <p><b>Approval Criteria</b></p> <p>1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium</p> |                                                                   |

|                                                                                                            |                                                                   |
|------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| Product Name:Alunbrig                                                                                      |                                                                   |
| Diagnosis                                                                                                  | National Comprehensive Cancer Network (NCCN) Recommended Regimens |
| Approval Length                                                                                            | 12 month(s)                                                       |
| Therapy Stage                                                                                              | Reauthorization                                                   |
| Guideline Type                                                                                             | Prior Authorization                                               |
| <p><b>Approval Criteria</b></p> <p>1 - Documentation of positive clinical response to Alunbrig therapy</p> |                                                                   |

## 2 . Revision History

| Date | Notes |
|------|-------|
|------|-------|

|            |                                      |
|------------|--------------------------------------|
| 10/30/2024 | Added Anaplastic Large Cell Lymphoma |
|------------|--------------------------------------|

Alyftrek



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-451219                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Guideline Name</b> | Alyftrek                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Pennsylvania (ACUPA)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 12/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                       |                       |
|-----------------------|-----------------------|
| Product Name:Alyftrek |                       |
| Approval Length       | 12 month(s)           |
| Therapy Stage         | Initial Authorization |
| Guideline Type        | Prior Authorization   |

### Approval Criteria

1 - Diagnosis of cystic fibrosis (CF)

**AND**

2 - Submission of laboratory results documenting that the patient has at least one of the following responsive mutations in the CFTR gene\*:

- F508del mutation
- A mutation that is responsive based on clinical data
- A mutation that is responsive based on in vitro data
- A mutation that is responsive based on extrapolated data

**AND**

3 - The patient is at least 6 years of age

**AND**

4 - Prescribed by or in consultation with a provider who specializes in the treatment of CF

|       |                                                                                                                                                                                                  |
|-------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Notes | *See Table 1 in Background for list of CFTR gene mutations responsive to Alyftrek. A complete up to date list of responsive mutations can be referenced in the Alyftrek Prescribing Information. |
|-------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                          |                     |
|--------------------------|---------------------|
| Product Name:Alyftrek    |                     |
| Approval Length          | 12 month(s)         |
| Therapy Stage            | Reauthorization     |
| Guideline Type           | Prior Authorization |
| <b>Approval Criteria</b> |                     |

1 - Documentation of positive clinical response to Alyftrek therapy (e.g., improved lung function, stable lung function)

## 2 . Background

### Benefit/Coverage/Program Information

**\*Table 1**

\*List of *CFTR* gene mutations responsive to Alyftrek. A complete up to date list of responsive mutations can be referenced in the Alyftrek Prescribing Information.

Based on clinical data\*\*

|          |        |         |        |       |             |  |
|----------|--------|---------|--------|-------|-------------|--|
| A455E    | G551D  | L1077P† | R352Q  | S549N | V754M       |  |
| D1152H   | G85E†  | L206W   | R75Q   | S549R | W1098C<br>† |  |
| F508del† | H1054D | M1101K† | S1159F | S945L | W1282R      |  |
| G1244E   | I336K  | R1066H  | S1251N | V562I | Y563N†      |  |

Based on in vitro data‡

|               |        |                  |        |        |                  |        |
|---------------|--------|------------------|--------|--------|------------------|--------|
| 1507_1515del9 | E116Q  | G424S            | I556V  | P140S  | R334L            | T1053I |
| 2183A→G       | E193K  | G463V            | I601F  | P205S  | R334Q            | T1086I |
| 3141del9      | E292K  | G480C            | I618T  | P499A  | R347H            | T1246I |
| 3195del6      | E403D  | G480S            | I807M  | P5L    | R347L            | T1299I |
| 3199del6      | E474K  | G551A            | I980K  | P574H  | R347P            | T338I  |
| 546insCTA     | E56K   | G551S            | K1060T | P67L   | R352W            | T351I  |
| A1006E        | E588V  | G576A            | K162E  | P750L  | R516G            | T604I  |
| A1067P        | E60K   | G576A;<br>R668C§ | K464E  | P99L   | R516S            | V1153E |
| A1067T        | E822K  | G622D            | L1011S | Q1100P | R553Q            | V1240G |
| A107G         | E92K   | G628R            | L102R  | Q1291R | R555G            | V1293G |
| A120T         | F1016S | G91R             | L1065P | Q1313K | R560S            | V201M  |
| A234D         | F1052V | G970D            | L1324P | Q237E  | R560T            | V232D  |
| A309D         | F1074L | G970S            | L1335P | Q237H  | R668C            | V392G  |
| A46D          | F1107L | H1085R           | L1480P | Q372H  | R74Q             | V456F  |
| A554E         | F191V  | H1375P           | L15P   | Q452P  | R74W             | V520F  |
| A559T         | F200I  | H139R            | L165S  | Q493R  | R74W;<br>D1270N§ | V603F  |

|                                                                                  |                   |                  |                  |                           |                            |              |
|----------------------------------------------------------------------------------|-------------------|------------------|------------------|---------------------------|----------------------------|--------------|
| A559V                                                                            | F311del           | H199R            | L320V            | Q552P                     | R74W;<br>V201M§            | W361R        |
| A561E                                                                            | F311L             | H199Y            | L333F            | Q98R                      | R74W;<br>V201M;<br>D1270N§ | Y1014C       |
| A613T                                                                            | F508C             | H609R            | L333H            | R1048G                    | R75L                       | Y1032C       |
| A62P                                                                             | F508C;<br>S1251N§ | H620P            | L346P            | R1066C                    | R751L                      | Y109N        |
| A72D                                                                             | F575Y             | H620Q            | L441P            | R1066L                    | R792G                      | Y161D        |
| C491R                                                                            | F587I             | H939R            | L453S            | R1066M                    | R933G                      | Y161S        |
| D110E                                                                            | G1047R            | H939R;<br>H949L  | L619S            | R1070Q                    | S1045Y                     | Y301C        |
| D110H                                                                            | G1061R            | I1027T           | L967S            | R1070W                    | S108F                      | Y569C        |
| D1270N                                                                           | G1069R            | I105N            | L997F            | R1162L                    | S1118F                     | Y913C        |
| D1445N                                                                           | G1123R            | I1139V           | M1101R           | R117C                     | S1159P                     |              |
| D192G                                                                            | G1247R            | I1234Vdel6<br>aa | M1137V           | R117C;<br>G576A;<br>R668C | S1235R                     |              |
| D443Y                                                                            | G1249R            | I125T            | M150K            | R117G                     | S1255P                     |              |
| D443Y;<br>G576A;<br>R668C§                                                       | G126D             | I331N            | M26SR            | R117L                     | S13F                       |              |
| D513G                                                                            | G1349D            | I331N            | M265R            | R117L                     | S341P                      |              |
| D565G                                                                            | G149R             | I1366N           | M952I            | R117P                     | S364P                      |              |
| D579G                                                                            | G178E             | I1398S           | M952T            | R1283M                    | S492F                      |              |
| D614G                                                                            | G178R             | I148N            | N1088D           | R1283S                    | S549I                      |              |
| D836Y                                                                            | G194R             | I148T            | N1303I           | R170H                     | S589N                      |              |
| D924N                                                                            | G194V             | I175V            | N1303K‡          | R258G                     | S737F                      |              |
| D979V                                                                            | G27E              | I502T            | N186K            | R297Q                     | S912L                      |              |
| D993Y                                                                            | G27R              | I506L            | N187K            | R31C                      | S977F                      |              |
| E116K                                                                            | G314E             | I506T            | N418S            | R31L                      | T1036N                     |              |
| Based on extrapolation¶                                                          |                   |                  |                  |                           |                            |              |
| 1341G→A                                                                          | 2789+2ins<br>A    | 3041-<br>15T→G   | 3849+10kbC<br>→T | 3850-<br>3T→G             | 5T; TG13                   | 711+3A<br>→G |
| 1898+3A→G                                                                        | 2789+5G<br>→A     | 3272-<br>26A→G   | 3849+4A→G        | 4005+2T<br>→C             | 621+3A<br>→G               | E831X        |
| 2752-<br>26A→G                                                                   | 296+28A<br>→G     | 3600G→A          | 3849+40A→<br>G   | 5T; TG12                  |                            |              |
| ** Clinical data is obtained from Trial 1, NCT05033080 and Trial 2, NCT05076149. |                   |                  |                  |                           |                            |              |

† This mutation is also predicted to be responsive by FRT assay with Alyftrek.

‡ The *N1303K* mutation is predicted to be responsive only by HBE assay. All other mutations predicted to be responsive with in vitro data are supported by FRT assay.

§ Complex/compound mutations where a single allele of the *CFTR* gene has multiple mutations; these exist independent of the presence of mutations on the other allele.

¶ Efficacy is extrapolated to certain non-canonical splice mutations because clinical trials in all mutations in this subgroup are infeasible and these mutations are not amenable to interrogation by FRT system.

### 3 . Revision History

| Date       | Notes      |
|------------|------------|
| 11/12/2025 | Removed MI |



Ampyra



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-133253                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Guideline Name</b> | Ampyra                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 11/1/2023 |
|-----------------|-----------|

## 1 . Criteria

|                                                      |                     |
|------------------------------------------------------|---------------------|
| Product Name: Brand Ampyra, generic dalfampridine ER |                     |
| Approval Length                                      | 12 month(s)         |
| Guideline Type                                       | Prior Authorization |
| Approval Criteria                                    |                     |

1 - Diagnosis of multiple sclerosis

## 2 . Revision History

| Date      | Notes                                                          |
|-----------|----------------------------------------------------------------|
| 9/19/2023 | Updated criteria to only require diagnosis to allow for DX2RX. |

## Anthelmintics



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-421299                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Guideline Name</b> | Anthelmintics                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Pennsylvania (ACUPA)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 11/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                                   |                                                                        |
|-----------------------------------|------------------------------------------------------------------------|
| Product Name: Generic albendazole |                                                                        |
| Approval Length                   | *Approve for 1 month, **Approve for 6 months, ***Approve for 12 months |
| Guideline Type                    | Prior Authorization                                                    |

### Approval Criteria

1 - Diagnosis of ONE of the following\*:

- Enterobius vermicularis (pinworm)
- Ascariasis (roundworm)
- Toxocariasis (roundworm)
- Trichinellosis
- Trichuriasis (whipworm)
- Capillariasis
- Baylisascaris
- Clonorchiasis (liver flukes)
- Gnathostomiasis
- Strongyloidiasis
- Loiasis
- Opisthorchiasis
- Anisakiasis

**OR**

2 - Diagnosis of ONE of the following\*\*:

- Taeniasis or Cysticercosis/Neurocysticercosis
- Hydatid Disease [Echinococcosis (Tapeworm)]
- Ancylostoma/Necatoriasis (Hookworm)

**OR**

3 - Diagnosis of microsporidiosis not caused by Enterocytozoon bienersi or Vittaforma corneae\*\*\*

|                          |                                              |
|--------------------------|----------------------------------------------|
| Product Name: Emverm     |                                              |
| Approval Length          | *Approve for 1 month, **Approve for 6 months |
| Guideline Type           | Prior Authorization                          |
| <b>Approval Criteria</b> |                                              |

**1 - Diagnosis of ONE of the following\*:**

- Enterobius vermicularis (pinworm)
- Ancylostoma/Necatoriasis (Hookworm)
- Ascariasis (roundworm)
- Toxocariasis (roundworm)
- Trichinellosis
- Trichuriasis (whipworm)
- Capillariasis
- Baylisascaris

**OR**

**2 - Diagnosis of hydatid Disease [Echinococcosis (Tapeworm)]\*\***

## 2 . Revision History

| Date       | Notes                                                                                   |
|------------|-----------------------------------------------------------------------------------------|
| 10/15/2025 | Updated formularies. Removed step thru OTC pyrantel pamoate. Reformatted for simplicity |

## Anticonvulsants



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-354248                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Guideline Name</b> | Anticonvulsants                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 9/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                                                                                      |                     |
|--------------------------------------------------------------------------------------|---------------------|
| Product Name: Brand Aptiom, generic eslicarbazepine, Briviact tabs/oral soln, Xcopri |                     |
| Approval Length                                                                      | 12 month(s)         |
| Guideline Type                                                                       | Prior Authorization |
| Approval Criteria                                                                    |                     |

**1** - For continuation of prior therapy for a seizure disorder

**OR**

**2** - ALL of the following:

**2.1** Diagnosis of partial-onset seizures

**AND**

**2.2** History of greater than or equal to 8 week trial of at least TWO of the following (any release formulation qualifies) confirmed by claims history or submitted medical records:

- Carbamazepine (e.g., generic Tegretol)
- Divalproex (e.g., generic Depakote)
- Gabapentin (e.g., generic Neurontin)
- Lacosamide (e.g. generic Vimpat)
- Lamotrigine (e.g., generic Lamictal)
- Levetiracetam (e.g., generic Keppra)
- Oxcarbazepine (e.g., generic Trileptal)
- Phenytoin (e.g., generic Dilantin)
- Pregabalin (e.g., generic Lyrica)
- Topiramate (e.g., generic Topamax)
- Valproic acid (e.g., generic Depakene)
- Zonisamide (generic Zonegran)

**Product Name:**Brand Fycompa, generic perampanel

**Approval Length** 12 month(s)

**Guideline Type** Prior Authorization

**Approval Criteria**

**1** - For continuation of prior therapy for a seizure disorder

**OR**

**2** - ALL of the following:

**2.1** ONE of the following:

**2.1.1** Diagnosis of partial-onset seizures with or without secondarily generalized seizures

**OR**

**2.1.2** ALL of the following:

- Diagnosis of primary generalized tonic-clonic seizures
- Used as adjunctive therapy (defined as accessory treatment used in combination to enhance primary treatment)
- Not used as primary treatment

**AND**

**2.2** History of greater than or equal to 8 week trial of at least TWO of the following (any release formulation qualifies) confirmed by claims history or submitted medical records:

- Carbamazepine (e.g., generic Tegretol)
- Divalproex (e.g., generic Depakote)
- Gabapentin (e.g., generic Neurontin)
- Lacosamide (e.g. generic Vimpat)
- Lamotrigine (e.g., generic Lamictal)
- Levetiracetam (e.g., generic Keppra)
- Oxcarbazepine (e.g., generic Trileptal)
- Phenytoin (e.g., generic Dilantin)
- Pregabalin (e.g., generic Lyrica)
- Topiramate (e.g., generic Topamax)
- Valproic acid (e.g., generic Depakene)
- Zonisamide (generic Zonegran)

|                         |                     |
|-------------------------|---------------------|
| Product Name:Motpoly XR |                     |
| Approval Length         | 12 month(s)         |
| Guideline Type          | Prior Authorization |
| Approval Criteria       |                     |



**1** - For continuation of prior therapy for a seizure disorder

**OR**

**2** - ALL of the following:

**2.1** ONE of the following:

**2.1.1** Diagnosis of partial onset seizures

**OR**

**2.1.2** ALL of the following:

- Diagnosis of primary generalized tonic-clonic seizures
- Used as adjunctive therapy (defined as accessory treatment used in combination to enhance primary treatment)
- Not used as primary treatment

**AND**

**2.2** History of greater than or equal to 8 week trial of at least TWO of the following (any release formulation qualifies) confirmed by claims history or submitted medical records:

- Carbamazepine (e.g., generic Tegretol)
- Divalproex (e.g., generic Depakote)
- Gabapentin (e.g., generic Neurontin)
- Lacosamide (e.g. generic Vimpat)
- Lamotrigine (e.g., generic Lamictal)
- Levetiracetam (e.g., generic Keppra)
- Oxcarbazepine (e.g., generic Trileptal)
- Phenytoin (e.g., generic Dilantin)
- Pregabalin (e.g., generic Lyrica)
- Topiramate (e.g., generic Topamax)
- Valproic acid (e.g., generic Depakene)
- Zonisamide (generic Zonegran)

Product Name: Epidiolex

Approval Length      12 month(s)

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Prior Authorization |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1</b> - For continuation of prior therapy for a seizure disorder</p> <p style="text-align: center;"><b>OR</b></p> <p><b>2</b> - Diagnosis of seizures associated with Dravet syndrome or tuberous sclerosis complex</p> <p style="text-align: center;"><b>OR</b></p> <p><b>3</b> - BOTH of the following:</p> <p><b>3.1</b> Diagnosis of seizures associated with Lennox-Gastaut syndrome</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3.2</b> History of greater than or equal to 8 week trial of at least TWO generic anticonvulsants (e.g., divalproex, lamotrigine, topiramate, valproic acid)</p> |                     |

| Product Name:generic rufinamide, Brand Banzel                                                                                                                                                                                           |                     |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Approval Length                                                                                                                                                                                                                         | 12 month(s)         |
| Guideline Type                                                                                                                                                                                                                          | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - For continuation of prior therapy for a seizure disorder</p> <p style="text-align: center;"><b>OR</b></p> <p><b>2</b> - Diagnosis of seizures associated with Lennox-Gastaut syndrome</p> |                     |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                     |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Tiagabine                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                     |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | 12 month(s)         |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p>1 - For continuation of prior therapy for a seizure disorder</p> <p style="text-align: center;"><b>OR</b></p> <p>2 - ALL of the following:</p> <p>2.1 Diagnosis of partial-onset seizures</p> <p style="text-align: center;"><b>AND</b></p> <p>2.2 Used as adjunctive therapy (defined as accessory treatment used in combination to enhance primary treatment)</p> <p style="text-align: center;"><b>AND</b></p> <p>2.3 Not used as primary treatment</p> <p style="text-align: center;"><b>AND</b></p> <p>2.4 History of greater than or equal to 8 week trial of at least TWO of the following (any release formulation qualifies), confirmed by claims history or submitted medical records:</p> <ul style="list-style-type: none"> <li>• Carbamazepine (e.g., generic Tegretol)</li> <li>• Divalproex (e.g., generic Depakote)</li> <li>• Gabapentin (e.g., generic Neurontin)</li> <li>• Lacosamide (e.g. generic Vimpat)</li> <li>• Lamotrigine (e.g., generic Lamictal)</li> <li>• Levetiracetam (e.g., generic Keppra)</li> <li>• Oxcarbazepine (e.g., generic Trileptal)</li> <li>• Phenytoin (e.g., generic Dilantin)</li> <li>• Pregabalin (e.g., generic Lyrica)</li> </ul> |                     |

- Topiramate (e.g., generic Topamax)
- Valproic acid (e.g., generic Depakene)
- Zonisamide (generic Zonegran)

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                     |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name: Sympazan                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                     |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 12 month(s)         |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p>1 - For continuation of prior therapy for a seizure disorder</p> <p style="text-align: center;"><b>OR</b></p> <p>2 - ALL of the following:</p> <p>2.1 Diagnosis of seizures associated with Lennox-Gastaut syndrome (LGS)</p> <p style="text-align: center;"><b>AND</b></p> <p>2.2 BOTH of the following:</p> <ul style="list-style-type: none"> <li>• Used as adjunctive therapy (defined as accessory treatment used in combination to enhance primary treatment)</li> <li>• Not used as primary treatment</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p>2.3 History of greater than or equal to 8 week trial of at least TWO of the following (any release formulation qualifies), confirmed by claims history or submitted medical records:</p> <ul style="list-style-type: none"> <li>• Clobazam (e.g. generic Onfi)</li> <li>• Divalproex (e.g., generic Depakote)</li> <li>• Lamotrigine (e.g., generic Lamictal)</li> <li>• Topiramate (e.g., generic Topamax)</li> <li>• Valproic acid (e.g., generic Depakene)</li> <li>• Felbamate (generic Felbatol)</li> </ul> |                     |

- Rufinamide (generic Banzel)

**AND**

**2.4** Prescriber provides a reason or special circumstance the patient cannot use clobazam (generic Onfi) tablets or suspension

**OR**

**3** - ALL of the following:

**3.1** Diagnosis of refractory partial onset seizures (four or more uncontrolled seizures per month after an adequate trial of at least two antiepileptic drugs)

**AND**

**3.2** BOTH of the following:

- Used as adjunctive therapy (defined as accessory treatment used in combination to enhance primary treatment)
- Not used as primary treatment

**AND**

**3.3** History of greater than or equal to 8 week trial of at least TWO of the following (any release formulation qualifies), confirmed by claims history or submitted medical records:

- Carbamazepine (e.g., generic Tegretol)
- Divalproex (e.g., generic Depakote)
- Gabapentin (e.g., generic Neurontin)
- Lacosamide (e.g. generic Vimpat)
- Lamotrigine (e.g., generic Lamictal)
- Levetiracetam (e.g., generic Keppra)
- Oxcarbazepine (e.g., generic Trileptal)
- Phenytoin (e.g., generic Dilantin)
- Pregabalin (e.g., generic Lyrica)
- Topiramate (e.g., generic Topamax)
- Valproic acid (e.g., generic Depakene)
- Zonisamide (generic Zonegran)

**AND**

**3.4** Prescriber provides a reason or special circumstance the patient cannot use generic clobazam tablets or suspension

**OR**

**4** - ALL of the following:

- Diagnosis of Dravet syndrome
- Patient is currently taking Diacomit
- Prescriber provides a reason or special circumstance the patient cannot use generic clobazam tablets or suspension

Product Name: Brand Sabril powd pack, Brand Vigadrone powd pack, generic vigabatrin powd pack, generic Vigpoder powd pack

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

**1** - For continuation of prior therapy for a seizure disorder

**OR**

**2** - Diagnosis of infantile spasms

**OR**

**3** - ALL of the following:

**3.1** Diagnosis of complex partial seizures

**AND**

**3.2** Used as adjunctive therapy (defined as accessory treatment used in combination to enhance primary treatment)

**AND**

**3.3** Not used as primary treatment

**AND**

**3.4** History of greater than or equal to 8 week trial of at least TWO of the following (any release formulation qualifies), confirmed by claims history or submitted medical records:

- Carbamazepine (e.g., generic Tegretol)
- Divalproex (e.g., generic Depakote)
- Gabapentin (e.g., generic Neurontin)
- Lamotrigine (e.g., generic Lamictal)
- Levetiracetam (e.g., generic Keppra)
- Oxcarbazepine (e.g., generic Trileptal)
- Phenytoin (e.g., generic Dilantin)
- Pregabalin (e.g., generic Lyrica)
- Topiramate (e.g., generic Topamax)
- Valproic acid (e.g., generic Depakene)
- Zonisamide (generic Zonegran)

|                                                                                                     |                     |
|-----------------------------------------------------------------------------------------------------|---------------------|
| Product Name: Brand Sabril tablets, Brand Vigadrone tablets, generic vigabatrin tablets             |                     |
| Approval Length                                                                                     | 12 month(s)         |
| Guideline Type                                                                                      | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p>1 - For continuation of prior therapy for a seizure disorder</p> |                     |

**OR**

**2 - ALL of the following:**

**2.1** Diagnosis of complex partial seizures

**AND**

**2.2** Used as adjunctive therapy (defined as accessory treatment used in combination to enhance primary treatment)

**AND**

**2.3** Not used as primary treatment

**AND**

**2.4** History of greater than or equal to 8 week trial of at least TWO of the following (any release formulation qualifies), confirmed by claims history or submitted medical records:

- Carbamazepine (e.g., generic Tegretol)
- Divalproex (e.g., generic Depakote)
- Gabapentin (e.g., generic Neurontin)
- Lamotrigine (e.g., generic Lamictal)
- Levetiracetam (e.g., generic Keppra)
- Oxcarbazepine (e.g., generic Trileptal)
- Phenytoin (e.g., generic Dilantin)
- Pregabalin (e.g., generic Lyrica)
- Topiramate (e.g., generic Topamax)
- Valproic acid (e.g., generic Depakene)
- Zonisamide (generic Zonegran)

|                        |                     |
|------------------------|---------------------|
| Product Name: Vigafyde |                     |
| Approval Length        | 12 month(s)         |
| Guideline Type         | Prior Authorization |



**Approval Criteria**

1 - Diagnosis of infantile spasms

**OR**

2 - For continuation of prior therapy for a seizure disorder

Product Name:Diacomit

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

1 - For continuation of prior therapy for a seizure disorder

**OR**

2 - Diagnosis of Dravet syndrome and currently taking clobazam

Product Name:Fintepla

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

1 - For continuation of prior therapy for a seizure disorder

**OR**

**2 - BOTH of the following:**

**2.1** Diagnosis of seizures associated with Dravet syndrome

**AND**

**2.2** History of greater than or equal to 8-week trial of at least TWO of the following (any release formulation qualifies), confirmed by claims history or submitted medical records:

- Divalproex (e.g., generic Depakote)
- Levetiracetam (e.g., generic Keppra)
- Topiramate (e.g., generic Topamax)
- Valproic acid (e.g., generic Depakene)
- Zonisamide (generic Zonegran)

**OR**

**3 - BOTH of the following:**

**3.1** Diagnosis of seizures associated with Lennox-Gastaut syndrome

**AND**

**3.2** History of greater than or equal to 8 week trial of at least TWO of the following (any release formulation qualifies) confirmed by claims history or submitted medical records:

- Clobazam (generic Onfi)
- Divalproex (e.g., generic Depakote)
- Lamotrigine (e.g., generic Lamictal)
- Topiramate (e.g., generic Topamax)
- Valproic acid (e.g., generic Depakene)

|                      |                     |
|----------------------|---------------------|
| Product Name: Ztalmy |                     |
| Approval Length      | 12 month(s)         |
| Guideline Type       | Prior Authorization |
|                      |                     |

## Approval Criteria

1 - For continuation of prior therapy for a seizure disorder

**OR**

2 - ALL of the following:

**2.1** Diagnosis of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder confirmed with genetic testing

**AND**

**2.2** History of greater than or equal to 8-week trial of at least TWO of the following (any release formulation qualifies), confirmed by claims history or submitted medical records:

- Carbamazepine (e.g., generic Tegretol)
- Divalproex (e.g., generic Depakote)
- Gabapentin (e.g., generic Neurontin)
- Lamotrigine (e.g., generic Lamictal)
- Levetiracetam (e.g., generic Keppra)
- Oxcarbazepine (e.g., generic Trileptal)
- Phenytoin (e.g., generic Dilantin)
- Pregabalin (e.g., generic Lyrica)
- Topiramate (e.g., generic Topamax)
- Valproic acid (e.g., generic Depakene)
- Zonisamide (generic Zonegran)

## 2 . Revision History

| Date     | Notes                                                                                   |
|----------|-----------------------------------------------------------------------------------------|
| 8/5/2025 | Updated GPIs and product lists to add generic Aptiom and Fycompa, remove brand Gabitril |

Antipsoriatic Agents



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-173218                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Guideline Name</b> | Antipsoriatic Agents                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 4/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                                          |                     |
|------------------------------------------|---------------------|
| Product Name:generic calcitriol ointment |                     |
| Approval Length                          | 12 month(s)         |
| Guideline Type                           | Prior Authorization |
| Approval Criteria                        |                     |

**1 - Diagnosis of psoriasis**

**AND**

**2 - ONE of the following:**

**2.1** Failure to TWO medium to high potency corticosteroid topical treatments (see Background) as confirmed by claims history or submission of medical records

**OR**

**2.2** History of intolerance or contraindication to TWO medium to high potency corticosteroid topical treatments (see Background) (please specify intolerance or contraindication)

**AND**

**3 - ONE of the following:**

**3.1** Failure to ONE of the following as confirmed by claims history or submission of medical records:

- Calcipotriene cream
- Calcipotriene ointment

**OR**

**3.2** History of contraindication or intolerance to BOTH of the following (please specify intolerance or contraindication):

- Calcipotriene cream
- Calcipotriene ointment

## **2 . Background**

**Benefit/Coverage/Program Information****Table 1. Relative Potency of Selected Topical Corticosteroid Products**

| <b>Drug</b>                                                    | <b>Dosage Form</b>                                                              | <b>Strength</b>       |
|----------------------------------------------------------------|---------------------------------------------------------------------------------|-----------------------|
| <b>Super-High Potency (group 1)</b>                            |                                                                                 |                       |
| Augmented betamethasone dipropionate (Diprolene)               | Gel, Ointment, lotion                                                           | 0.05%                 |
| Clobetasol propionate (Clobex, Olux, Temovate, Temovate E)     | Cream, Ointment, Gel, Solution, Lotion, Shampoo, Spray<br>Aerosol, Foam Aerosol | 0.05%                 |
| Fluocinonide (Vanos)                                           | Cream                                                                           | 0.1%                  |
| Flurandrenolide (Cordran)                                      | Tape (roll)                                                                     | 4 mcg/cm <sup>2</sup> |
| Halobetasol propionate (Ultravate, Lexette)                    | Lotion, Cream, Ointment, Foam                                                   | 0.05%                 |
| <b>High Potency (group 2)</b>                                  |                                                                                 |                       |
| Amcinonide (Amcort)                                            | Ointment                                                                        | 0.1%                  |
| Augmented betamethasone dipropionate (Diprolene, Diprolene AF) | Cream, Lotion, Ointment                                                         | 0.05%                 |
| Betamethasone dipropionate                                     | Lotion, Ointment                                                                | 0.05%                 |
| Clobetasol propionate (Impoyz)                                 | Cream                                                                           | 0.025%                |
| Desoximetasone (Topicort)                                      | Cream, Ointment, Spray                                                          | 0.25%,                |
|                                                                | Gel                                                                             | 0.05%                 |
| Diflorasone diacetate (Psorcon)                                | Cream, Ointment                                                                 | 0.05%                 |
| Fluocinonide (Lidex, Lidex E)                                  | Cream, Gel, Ointment, Solution                                                  | 0.05%                 |
| Halcinonide (Halog)                                            | Cream, Ointment, Solution                                                       | 0.1%                  |

|                                                           |                           |        |
|-----------------------------------------------------------|---------------------------|--------|
| Halobetasol propionate (Bryhali)                          | Lotion                    | 0.01%  |
|                                                           |                           |        |
| <b>High Potency (group 3)</b>                             |                           |        |
| Amcinonide (Amcort)                                       | Cream, Lotion             | 0.1%   |
| Betamethasone valerate (Valisone)                         | Ointment                  | 0.1%   |
| Desoximetasone (Topicort)                                 | Cream, ointment           | 0.05%  |
| Diflorasone diacetate (Florone, Psorcon)                  | Cream                     | 0.05%  |
| Fluocinonide (Lidex-E)                                    | Cream                     | 0.05%  |
| Fluticasone propionate (Cutivate)                         | Ointment                  | 0.005% |
| Mometasone furoate (Elocon)                               | Ointment                  | 0.1%   |
| Triamcinolone acetonide (Aristocort HP, Kenalog, Triderm) | Cream, ointment           | 0.5%   |
|                                                           |                           |        |
| <b>Medium Potency (group 4)</b>                           |                           |        |
| Betamethasone dipropionate (sernivo)                      | Spray                     | 0.05%  |
| Clocortolone pivalate (Cloderm)                           | Cream                     | 0.1%   |
| Fluocinolone acetonide (Synalar)                          | Cream, Ointment           | 0.025% |
| Flurandrenolide (Cordran)                                 | Ointment                  | 0.05%  |
| Fluticasone propionate (Cutivate)                         | Cream, Lotion             | 0.05%  |
| Hydrocortisone valerate (Westcort)                        | Ointment                  | 0.2%   |
| Mometasone furoate (Elocon)                               | Cream, lotion, Solution   | 0.1%   |
| Triamcinolone acetonide (Aristocort, Kenalog)             | Cream, Lotion<br>Ointment | 0.1%   |
|                                                           | Ointment                  | 0.05%  |

### 3 . Revision History

| Date      | Notes                                                                                                                              |
|-----------|------------------------------------------------------------------------------------------------------------------------------------|
| 2/18/2025 | Removed calcipotriene cream and ointment as targets for guideline.<br>Added a step through either calcipotriene cream or ointment. |



## Antipsychotics



## Prior Authorization Guideline

|                       |                                                                                                         |
|-----------------------|---------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-288233                                                                                               |
| <b>Guideline Name</b> | Antipsychotics                                                                                          |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>Medicaid - Community &amp; State New Jersey (PSI2300)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 7/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                    |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------|
| Product Name: aripiprazole ODT, aripiprazole oral soln, Abilify Maintena, Abilify MyCite, generic aripiprazole tabs, Brand Abilify, Aristada, Aristada Initio, Caplyta, generic clozapine tabs, Brand Clozaril, clozapine ODT, Cobenfy, Fanapt, Fanapt Titration Pack, generic ziprasidone caps, Brand Geodon caps, generic paliperidone ER, Brand Invega, Invega Sustenna, Invega Trinza, Invega Hafyera, Brand Latuda, generic lurasidone, Lybalvi, molindone, Perseris, Rexulti, generic risperidone tabs/soln, Brand Risperdal, Brand Risperdal Consta, generic risperidone ER IM injection, Rykindo, risperidone ODT, Brand Saphris, generic asenapine, Secuado, generic quetiapine, Brand Seroquel, generic quetiapine ER, Brand Seroquel XR, Vraylar, generic olanzapine tabs, Brand Zyprexa tabs, generic olanzapine ODT, Brand Zyprexa Zydis, Versacloz, Abilify Asimtufii, Uzedy, Erzofri, Opipza |                                                                    |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Atypical Antipsychotics: Prior Authorization for Minimum Age Edit* |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | 12 month(s)                                                        |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Prior Authorization                                                |

## Approval Criteria

1 - ALL of the following:

1.1 The patient is unresponsive to other treatment modalities, unless contraindication (i.e., other medications or behavioral modification attempted)

**AND**

1.2 The patient has tried and failed all available preferred\*\* atypical antipsychotics that are Food and Drug Administration (FDA) approved for the patient's age^

**AND**

1.3 One of the following:

1.3.1 Patient has ONE of the following diagnoses:

- Schizophrenia or schizoaffective disorder
- Autism
- Bipolar disorder

**OR**

1.3.2 Patient displays symptoms of aggression as a symptom of developmental delay, Tourette's syndrome or chronic tics, oppositional defiant disorder, or conduct disorder

|       |                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|-------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Notes | <p>*See Table 1 in the Background section for Minimum Age Edits</p> <p>**PDL link: <a href="https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html</a></p> <p>^NJ Psych Panel (any mental health prescriber) is not subject to this criterion.</p> |
|-------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                                                                       |                                                                |
|-----------------------------------------------------------------------|----------------------------------------------------------------|
| Product Name:generic risperidone oral soln, Brand Risperdal oral soln |                                                                |
| Diagnosis                                                             | Risperidone Oral Solution: Authorization for Maximum Age Edit* |
| Approval Length                                                       | 12 month(s)                                                    |
| Guideline Type                                                        | Prior Authorization                                            |

### **Approval Criteria**

**1** - ALL of the following:

**1.1** Patient has ONE of the following:

**1.1.1** Schizophrenia or schizoaffective disorder

**OR**

**1.1.2** Bipolar disorder

**OR**

**1.1.3** Autism

**OR**

**1.1.4** BOTH of the following:

**1.1.4.1** The use of this drug is supported by information from ONE of the following appropriate compendia:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopoeia-National Formulary (USP-NF)

**AND**

**1.1.4.2** The drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plan's program

**AND**

**1.2** The drug is being prescribed within the manufacturer's published dosing guidelines or falls within dosing guidelines found in ONE of the following compendia of current literature:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopoeia-National Formulary (USP-NF)

**AND**

**1.3** ONE of the following^:

**1.3.1** The patient is unable to swallow the oral solid preferred alternatives\*\*

**OR**

**1.3.2** One of the following:

**1.3.2.1** Failure to a majority (not more than 3) of the oral solid preferred\*\* alternatives as confirmed by claims history or submission of medical records

**OR**

**1.3.2.2** History of contraindication or intolerance to a majority (not more than 3) of the oral solid preferred\*\* alternatives (please specify contraindication or intolerance)

|       |                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|-------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Notes | <p>*See Table 2 in the Background section for UHC C&amp;S Plan Maximum Age Edits</p> <p>**PDL link: <a href="https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html</a></p> <p>^NJ Psych Panel (any mental health prescriber) is not subject to this criterion.</p> |
|-------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                                |                     |
|--------------------------------|---------------------|
| Product Name: Abilify Maintena |                     |
| Approval Length                | 12 month(s)         |
| Guideline Type                 | Prior Authorization |

### Approval Criteria

1 - ALL of the following:

1.1 Patient has ONE of the following diagnoses:

- Schizophrenia or schizoaffective disorder
- Bipolar disorder

**AND**

1.2 ONE of the following^:

1.2.1 Patient is non-adherent with oral atypical antipsychotic dosage forms

**OR**

1.2.2 Patient has established tolerability with oral aripiprazole

**OR**

1.2.3 Patient is unable to take oral solid alternatives

|       |                                                                                  |
|-------|----------------------------------------------------------------------------------|
| Notes | ^NJ Psych Panel (any mental health prescriber) is not subject to this criterion. |
|-------|----------------------------------------------------------------------------------|

|                                                                                                                                             |                     |
|---------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Aristada, Aristada Initio                                                                                                      |                     |
| Approval Length                                                                                                                             | 12 month(s)         |
| Guideline Type                                                                                                                              | Prior Authorization |
| <h3>Approval Criteria</h3> <p>1 - ALL of the following:</p> <p>1.1 Patient has a diagnosis of schizophrenia or schizoaffective disorder</p> |                     |

**AND**

**1.2** ONE of the following^:

**1.2.1** Patient is non-adherent with oral atypical antipsychotic dosage forms

**OR**

**1.2.2** Patient has established tolerability with oral aripiprazole

**OR**

**1.2.3** Patient is unable to take oral solid alternatives

|       |                                                                                  |
|-------|----------------------------------------------------------------------------------|
| Notes | ^NJ Psych Panel (any mental health prescriber) is not subject to this criterion. |
|-------|----------------------------------------------------------------------------------|

|                                                                                                                                                                                                                                                                                                                                                                               |                     |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name: Invega Hafyera                                                                                                                                                                                                                                                                                                                                                  |                     |
| Approval Length                                                                                                                                                                                                                                                                                                                                                               | 12 month(s)         |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Patient has a diagnosis of schizophrenia or schizoaffective disorder</p> <p><b>AND</b></p> <p><b>2</b> - ONE of the following^:</p> <p><b>2.1</b> Patient has been established on once-a-month paliperidone palmitate extended-release injectable suspension (e.g., Invega Sustenna) for at least 4 months</p> <p><b>OR</b></p> |                     |

|                                                                                                                                                                                     |                                                                                  |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|
| <b>2.2</b> Patient has been established on every-three-month paliperidone palmitate extended-release injectable suspension (e.g., Invega Trinza) for at least one three-month cycle |                                                                                  |
| Notes                                                                                                                                                                               | ^NJ Psych Panel (any mental health prescriber) is not subject to this criterion. |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                  |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|
| Product Name:Invega Sustenna                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                  |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 12 month(s)                                                                      |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Prior Authorization                                                              |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - ALL of the following:</p> <p><b>1.1</b> Patient has a diagnosis of schizophrenia or schizoaffective disorder</p> <p style="text-align: center;"><b>AND</b></p> <p><b>1.2</b> ONE of the following^:</p> <p><b>1.2.1</b> Patient is non-adherent with oral atypical antipsychotic dosage forms</p> <p style="text-align: center;"><b>OR</b></p> <p><b>1.2.2</b> Patient has established tolerability with oral paliperidone or oral risperidone</p> <p style="text-align: center;"><b>OR</b></p> <p><b>1.2.3</b> Patient is unable to take oral solid alternatives</p> |                                                                                  |
| Notes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | ^NJ Psych Panel (any mental health prescriber) is not subject to this criterion. |

|                            |             |
|----------------------------|-------------|
| Product Name:Invega Trinza |             |
| Approval Length            | 12 month(s) |

|                                                                                                                                                                                                                                                                                                                                |                                                                                  |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|
| Guideline Type                                                                                                                                                                                                                                                                                                                 | Prior Authorization                                                              |
| <p><b>Approval Criteria</b></p> <p>1 - ALL of the following:</p> <p>1.1 Patient has a diagnosis of schizophrenia or schizoaffective disorder</p> <p style="text-align: center;"><b>AND</b></p> <p>1.2 Patient has been established on Invega Sustenna for at least 4 consecutive months prior to initiating Invega Trinza^</p> |                                                                                  |
| Notes                                                                                                                                                                                                                                                                                                                          | ^NJ Psych Panel (any mental health prescriber) is not subject to this criterion. |

|                                                                                                                                                                                                                                                                                                                                                                                                                                          |                     |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Perseris                                                                                                                                                                                                                                                                                                                                                                                                                    |                     |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                          | 12 month(s)         |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                           | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p>1 - ALL of the following:</p> <p>1.1 Patient has a diagnosis of schizophrenia or schizoaffective disorder</p> <p style="text-align: center;"><b>AND</b></p> <p>1.2 ONE of the following^:</p> <p>1.2.1 Patient is non-adherent with oral atypical antipsychotic dosage forms</p> <p style="text-align: center;"><b>OR</b></p> <p>1.2.2 Patient has established tolerability with oral risperidone</p> |                     |



|                                                                |                                                                                  |
|----------------------------------------------------------------|----------------------------------------------------------------------------------|
| <b>OR</b>                                                      |                                                                                  |
| <b>1.2.3</b> Patient is unable to take oral solid alternatives |                                                                                  |
| Notes                                                          | ^NJ Psych Panel (any mental health prescriber) is not subject to this criterion. |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                  |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|
| Product Name: Brand Risperdal Consta, generic risperidone ER IM injection                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                  |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | 12 month(s)                                                                      |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Prior Authorization                                                              |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - ALL of the following:</p> <p><b>1.1</b> Patient has ONE of the following diagnoses:</p> <ul style="list-style-type: none"> <li>Schizophrenia or schizoaffective disorder</li> <li>Bipolar disorder</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>1.2</b> ONE of the following^:</p> <p><b>1.2.1</b> Patient is non-adherent with oral atypical antipsychotic dosage forms</p> <p style="text-align: center;"><b>OR</b></p> <p><b>1.2.2</b> Patient has established tolerability with oral risperidone</p> <p style="text-align: center;"><b>OR</b></p> <p><b>1.2.3</b> Patient is unable to take oral solid alternatives</p> |                                                                                  |
| Notes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | ^NJ Psych Panel (any mental health prescriber) is not subject to this criterion. |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                  |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|
| Product Name: Abilify Asimtufii                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                  |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 12 month(s)                                                                      |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Prior Authorization                                                              |
| <p><b>Approval Criteria</b></p> <p>1 - Patient has ONE of the following diagnoses:</p> <ul style="list-style-type: none"> <li>Schizophrenia or schizoaffective disorder</li> <li>Bipolar disorder</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p>2 - ONE of the following^:</p> <ul style="list-style-type: none"> <li>Patient is non-adherent with oral atypical antipsychotic dosage forms</li> <li>Patient has established tolerability with oral aripiprazole</li> <li>Patient is unable to take oral solid alternatives</li> </ul> |                                                                                  |
| Notes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | ^NJ Psych Panel (any mental health prescriber) is not subject to this criterion. |

|                                                                                                                                                                                                 |                     |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name: Uzedly                                                                                                                                                                            |                     |
| Approval Length                                                                                                                                                                                 | 12 month(s)         |
| Guideline Type                                                                                                                                                                                  | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p>1 - Patient has a diagnosis of schizophrenia or schizoaffective disorder</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - ONE of the following^:</p> |                     |

|                                                                                                                                                                                                                                                              |                                                                                  |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|
| <ul style="list-style-type: none"> <li>• Patient is non-adherent with oral atypical antipsychotic dosage forms</li> <li>• Patient has established tolerability with oral risperidone</li> <li>• Patient is unable to take oral solid alternatives</li> </ul> |                                                                                  |
| Notes                                                                                                                                                                                                                                                        | ^NJ Psych Panel (any mental health prescriber) is not subject to this criterion. |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                  |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|
| Product Name: Rykindo                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                  |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | 12 month(s)                                                                      |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Prior Authorization                                                              |
| <p><b>Approval Criteria</b></p> <p>1 - Patient has ONE of the following diagnoses:</p> <ul style="list-style-type: none"> <li>• Schizophrenia or schizoaffective disorder</li> <li>• Bipolar disorder</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p>2 - ONE of the following^:</p> <ul style="list-style-type: none"> <li>• Patient is non-adherent with oral atypical antipsychotic dosage forms</li> <li>• Patient has established tolerability with oral risperidone</li> <li>• Patient is unable to take oral solid alternatives</li> </ul> |                                                                                  |
| Notes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | ^NJ Psych Panel (any mental health prescriber) is not subject to this criterion. |

|                              |                       |
|------------------------------|-----------------------|
| Product Name: Abilify MyCite |                       |
| Approval Length              | 12 month(s)           |
| Therapy Stage                | Initial Authorization |
| Guideline Type               | Prior Authorization   |
|                              |                       |

## **Approval Criteria**

**1** - ALL of the following:

**1.1** Patient has ONE of the following diagnoses:

- Schizophrenia or schizoaffective disorder
- Bipolar disorder
- Autism
- Major depressive disorder
- Tourette's

**AND**

**1.2** Submission of medical records documenting the patient is currently prescribed aripiprazole and tolerates the medication<sup>^</sup>

**AND**

**1.3** Submission of medical records documenting the patient's adherence to aripiprazole is less than 80 percent within the past 6 months (medication adherence percentage is defined as the number of pills absent in a given time period divided by the number of pills prescribed during that same time, multiplied by 100)<sup>^</sup>

**AND**

**1.4** ALL of the following strategies (if applicable to the patient) to improve patient adherence have been tried without success<sup>^</sup>:

- Utilization of a pill box
- Utilization of a smart phone reminder (ex. alarm, application, or text reminder)
- Involving family members or friends to assist
- Coordinating timing of dose to coincide with dosing of another daily medication

**AND**

**1.5** Submission of medical records documenting patient has experienced life-threatening or potentially life-threatening symptoms, or has experienced a severe worsening of symptoms leading to a hospitalization which was attributed to the lack of adherence to aripiprazole<sup>^</sup>

**AND**

**1.6** Prescriber acknowledges that Abilify MyCite has not been shown to improve patient adherence and attests that Abilify MyCite is medically necessary for the patient to maintain compliance, avoid life-threatening worsening of symptoms, and reduce healthcare resources utilized due to lack of adherence^

**AND**

**1.7** Prescriber agrees to track and document adherence of Abilify MyCite through software provided by the manufacturer^

**AND**

**1.8** One of the following^:

**1.8.1** History of failure to TWO of the following as confirmed by claims history or submission of medical records:

- Abilify Maintena
- Invega Sustenna
- Risperidone ER injection (generic Risperdal Consta)
- Aristada
- Perseris

**OR**

**1.8.2** History of contraindication, intolerance, reason or special circumstance they cannot use ALL of the following (please specify contraindication, intolerance, reason or special circumstance):

- Abilify Maintena
- Invega Sustenna
- Risperidone ER injection (generic Risperdal Consta)
- Aristada
- Perseris

**OR**

**2** - One of the following

**2.1** The patient has been receiving treatment with the requested non-preferred behavioral health medication and is new to the plan (enrollment effective date within the past 90 days)

**OR**

**2.2** The patient is currently receiving treatment with the requested non-preferred behavioral health medication in the hospital and must continue upon discharge

|       |                                                                                  |
|-------|----------------------------------------------------------------------------------|
| Notes | ^NJ Psych Panel (any mental health prescriber) is not subject to this criterion. |
|-------|----------------------------------------------------------------------------------|

|                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                             |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Product Name: Abilify MyCite^                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                             |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                        | 12 month(s)                                                                                                                                                 |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                          | Reauthorization                                                                                                                                             |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                         | Prior Authorization                                                                                                                                         |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation that patient is clinically stable on Abilify MyCite</p> <p><b>AND</b></p> <p><b>2</b> - Submission of medical records documenting that the use of Abilify MyCite has increased adherence to 80 percent or more</p> <p><b>AND</b></p> <p><b>3</b> - Prescriber attests that the patient requires the continued use of Abilify MyCite to remain adherent</p> |                                                                                                                                                             |
| Notes                                                                                                                                                                                                                                                                                                                                                                                                                  | ^NJ Psych Panel Providers (any mental health prescriber) would override non-preferred status and are only subject to initial authorization diagnosis check. |

|                      |                     |
|----------------------|---------------------|
| Product Name:Vraylar |                     |
| Approval Length      | 12 month(s)         |
| Guideline Type       | Prior Authorization |

  

**Approval Criteria**

**1 - BOTH of the following:**

**1.1** Patient has a diagnosis of ONE of the following:

- Mania or mixed episodes associated with Bipolar Disorder
- Major depressive disorder (MDD)

**AND**

**1.2** ONE of the following^:

- Failure to three preferred\* alternatives, one of which must be aripiprazole, as confirmed by claims history or submission of medical records
- History of contraindication or intolerance to three preferred\* alternatives, one of which must be aripiprazole (please specify contraindication or intolerance)

**OR**

**2 - BOTH of the following:**

**2.1** Patient has a diagnosis of schizophrenia or schizoaffective disorder

**AND**

**2.2** ONE of the following^:

**2.2.1** Failure to THREE preferred atypical antipsychotics\*, which must include both aripiprazole and lurasidone, as confirmed by claims history or submission of medical records

**OR**

**2.2.2** History of contraindication or intolerance to THREE preferred atypical antipsychotics\*, which must include both aripiprazole and lurasidone (please specify contraindication or intolerance)

**OR**

**3** - BOTH of the following:

**3.1** Patient has a diagnosis of depressive episodes associated with Bipolar I Disorder (bipolar depression)

**AND**

**3.2** ONE of the following^:

**3.2.1** Failure to ALL of the following as confirmed by claims history or submission of medical records:

- Fluoxetine used in combination with olanzapine
- Lurasidone
- Quetiapine

**OR**

**3.2.2** History of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):

- Fluoxetine used in combination with olanzapine
- Lurasidone
- Quetiapine

**OR**

**4** - ONE of the following:

- The patient has been receiving treatment with the requested non-preferred behavioral health medication and is new to the plan (enrollment effective date within the past 90 days)



|                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                                                                                                               |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"> <li>The patient is currently receiving treatment with the requested non-preferred behavioral health medication in the hospital and must continue upon discharge</li> </ul> |                                                                                                                                                                                                                                                                                                                                                               |
| Notes                                                                                                                                                                                                         | <p>*PDL link: <a href="https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html</a></p> <p>^NJ Psych Panel (any mental health prescriber) is not subject to this criterion.</p> |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                     |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Cobenfy                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                     |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 12 month(s)         |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1 - BOTH of the following:</b></p> <p><b>1.1</b> Patient has a diagnosis of schizophrenia or schizoaffective disorder</p> <p style="text-align: center;"><b>AND</b></p> <p><b>1.2 ONE of the following^:</b></p> <p><b>1.2.1</b> Failure to THREE preferred atypical antipsychotics*, which must include both aripiprazole and lurasidone, as confirmed by claims history or submission of medical records</p> <p style="text-align: center;"><b>OR</b></p> <p><b>1.2.2</b> History of contraindication or intolerance to THREE preferred atypical antipsychotics*, which must include both aripiprazole and lurasidone (please specify contraindication or intolerance)</p> <p style="text-align: center;"><b>OR</b></p> <p><b>2 - ONE of the following:</b></p> |                     |

|                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                               |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"> <li>The patient has been receiving treatment with the requested non-preferred behavioral health medication and is new to the plan (enrollment effective date within the past 90 days)</li> <li>The patient is currently receiving treatment with the requested non-preferred behavioral health medication in the hospital and must continue upon discharge</li> </ul> |                                                                                                                                                                                                                                                                                                                                                               |
| Notes                                                                                                                                                                                                                                                                                                                                                                                                    | <p>*PDL link: <a href="https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html</a></p> <p>^NJ Psych Panel (any mental health prescriber) is not subject to this criterion.</p> |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                            |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|
| Product Name: Caplyta                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                            |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Caplyta Requests Exceeding Quantity Limit* |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 12 month(s)                                |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Quantity Limit                             |
| <p><b>Approval Criteria</b></p> <p><b>1 - ONE of the following:</b></p> <p><b>1.1</b> The requested drug must be used for a Food and Drug Administration (FDA)-approved indication</p> <p style="text-align: center;"><b>OR</b></p> <p><b>1.2</b> The use of this drug is supported by information from ONE of the following appropriate compendia of current literature:</p> <ul style="list-style-type: none"> <li>American Hospital Formulary Service Drug Information</li> <li>National Comprehensive Cancer Network Drugs and Biologics Compendium</li> <li>Thomson Micromedex DrugDex</li> <li>Clinical pharmacology</li> <li>United States Pharmacopoeia-National Formulary (USP-NF)</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>2 - ONE of the following:</b></p> |                                            |

**2.1** The drug is being prescribed within the manufacturer's published dosing guidelines

**OR**

**2.2** The requested dose falls within dosing guidelines found in ONE of the following compendia of current literature:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopoeia-National Formulary (USP-NF)

**AND**

**3** - The requested dosage cannot be achieved using the plan accepted quantity limit of a different dose or formulation

**AND**

**4** - The drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plans' program

**AND**

**5** - Physician has provided rationale for needing to exceed the quantity limit of one capsule per day, at a maximum dose of 42 mg (NOTE: The treatment effect of Caplyta at doses higher than 42 mg daily versus placebo was NOT statistically significant in clinical trials)

|       |                                                                                                                                   |
|-------|-----------------------------------------------------------------------------------------------------------------------------------|
| Notes | *Caplyta requests should be reviewed using the Non-Preferred criteria . This section is for Caplyta quantity limit requests only. |
|-------|-----------------------------------------------------------------------------------------------------------------------------------|

Product Name: aripiprazole ODT, aripiprazole oral soln, Brand Abilify, Caplyta, Brand Clozaril, clozapine ODT, Fanapt, Fanapt Titration Pack, Brand Geodon caps, Brand Invega, Brand Latuda, Lybalvi, molindone, Rexulti, Brand Risperdal, Brand Saphris, generic asenapine, Secuado, Brand Seroquel, generic quetiapine ER, Brand Seroquel XR, Brand Zyprexa tabs, Versacloz, Brand Zyprexa Zydis, haloperidol oral conc, Brand Haldol Decanoate, chlorpromazine inj, chlorpromazine oral soln, Erzofri, Opipza

|           |               |
|-----------|---------------|
| Diagnosis | Non-Preferred |
|-----------|---------------|

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                     |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | 12 month(s)         |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1 - ALL of the following:</b></p> <p><b>1.1 ONE of the following(*, ^):</b></p> <p><b>1.1.1</b> Patient must demonstrate failure to a majority (not more than three) of the preferred formulary/preferred drug list (PDL) alternatives, one of which must be aripiprazole, for the given diagnosis as confirmed by claims history or submission of medical records - Prior trials of formulary/PDL alternatives must sufficiently demonstrate that the formulary/PDL alternatives are either ineffective or inappropriate at the time of the request</p> <p style="text-align: center;"><b>OR</b></p> <p><b>1.1.2</b> Patient must demonstrate intolerance to a majority (not more than three) of the preferred formulary/PDL alternatives, one of which must be aripiprazole, for the given diagnosis (please specify intolerance) - Prior trials of formulary/PDL alternatives must sufficiently demonstrate that the formulary/PDL alternatives are either ineffective or inappropriate at the time of the request</p> <p style="text-align: center;"><b>OR</b></p> <p><b>1.1.3</b> There are no preferred formulary alternatives for the requested drug</p> <p style="text-align: center;"><b>AND</b></p> <p><b>1.2</b> If the request is for a multi-source brand medication, ONE of the following^:</p> <p><b>1.2.1</b> The multi-source brand is being requested because of an adverse reaction, allergy, or sensitivity to a generic equivalent (specify the adverse reaction, allergy, or sensitivity)</p> <p style="text-align: center;"><b>OR</b></p> <p><b>1.2.2</b> The multi-source brand is being requested due to an incomplete response with the generic equivalent as documented by submission of medical records</p> |                     |

**OR**

**1.2.3** The multi-source brand is being requested because transition to a generic equivalent could result in destabilization of the patient

**OR**

**1.2.4** Special clinical circumstances exist that preclude the use of a generic version of the multi-source brand medication for the patient (document special clinical circumstance)

**AND**

**1.3** ONE of the following:

**1.3.1** The requested drug must be used for a Food and Drug Administration (FDA)-approved indication

**OR**

**1.3.2** The use of this drug is supported by information from ONE of the following appropriate compendia of current literature:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopoeia-National Formulary (USP-NF)

**AND**

**1.4** The drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plan's program

**OR**

**2** - The patient has been receiving treatment with the requested non-preferred behavioral health medication and is new to the plan (enrollment effective date within the past 90 days)

**OR**

**3** - The patient is currently receiving treatment with the requested non-preferred behavioral health medication in the hospital and must continue upon discharge

Notes

\*PDL link: <https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html>  
^NJ Psych Panel (any mental health prescriber) is not subject to this criterion.

## 2 . Background

### Benefit/Coverage/Program Information

**Table 1: Minimum Age Edits**

Based on FDA-approved uses, prior authorization is required for antipsychotic medications for members less than the following ages:

- Abilify Discmelt, Abilify oral solution – 6 years of age
- Abilify Maintena – 18 years of age
- Abilify MyCite – 18 years of age
- Abilify oral tablets – 6 years of age
- Abilify Asimtufii – 18 years of age
- Aristada – 18 years of age
- Caplyta – 18 years of age
- Clozaril – 18 years of age
- Cobenfy – 18 years of age
- Erzofri – 18 years of age
- Fanapt – 18 years of age
- Geodon – 18 years of age
- Invega – 12 years of age
- Invega Sustenna – 18 years of age
- Invega Trinza – 18 years of age
- Invega Hafyera – 18 years of age
- Latuda – 10 years of age
- Lybalvi – 18 years of age
- Molindone – 12 years of age
- Opienza – 6 years of age

- Perseris – 18 years of age
- Rexulti – 18 years of age
- Risperdal – 5 years of age
- Risperdal Consta – 18 years of age
- Rykindo – 18 years of age
- Saphris – 10 years of age
- Secuado – 18 years of age
- Seroquel, Seroquel XR – 10 years of age
- Uzedly – 18 years of age
- Vraylar – 18 years of age
- Zyprexa – 13 years of age
- Zyprexa Zydys – 6 years of age

**Table 2: Maximum Age Edits**

Prior authorization is required for atypical antipsychotic claims for members greater than the following ages:

- Risperidone oral solution: 7 years of age

### 3 . Revision History

| Date     | Notes                                                                                                        |
|----------|--------------------------------------------------------------------------------------------------------------|
| 6/3/2025 | Generic paliperidone ER tabs, generic olanzapine ODT and risperidone ODT removed from non-preferred section. |

Apokyn



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-127844                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Guideline Name</b> | Apokyn                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 9/1/2023 |
|-----------------|----------|

## 1 . Criteria

|                                                     |                       |
|-----------------------------------------------------|-----------------------|
| Product Name: Brand Apokyn, generic apomorphine hcl |                       |
| Approval Length                                     | 12 month(s)           |
| Therapy Stage                                       | Initial Authorization |
| Guideline Type                                      | Prior Authorization   |
|                                                     |                       |



## **Approval Criteria**

**1** - Diagnosis of Parkinson's disease

**AND**

**2** - Apokyn will be used as intermittent treatment for OFF episodes

**AND**

**3** - Prescribed by or in consultation with a neurologist or specialist in the treatment of Parkinson's disease

**AND**

**4** - Patient is currently on a stable dose of a carbidopa/levodopa-containing medication and will continue receiving treatment with a carbidopa/levodopa-containing medication while on therapy

**AND**

**5** - Patient continues to experience greater than or equal to 2 hours of OFF time per day despite optimal management of carbidopa/levodopa therapy including BOTH of the following:

- Taking carbidopa/levodopa on an empty stomach or at least one half-hour or more before or one hour after a meal or avoidance of high protein diet
- Dose and dosing interval optimization

**AND**

**6** - ONE of the following:

**6.1** Failure to TWO anti-Parkinson's disease therapies from the following adjunctive pharmacotherapy classes (trial must be from two different classes) confirmed by claims history or submitted medical records:

- Dopamine agonists (e.g., pramipexole, ropinirole)
- Catechol-O-methyl transferase (COMT) inhibitors (e.g., entacapone)

- Monoamine oxidase (MAO) B inhibitors (e.g., rasagiline, selegiline)

**OR**

**6.2** History of contraindication or intolerance to TWO anti-Parkinson's disease therapies from the following adjunctive pharmacotherapy classes (contraindication/intolerance must be from two different classes; please specify intolerance or contraindication):

- Dopamine agonists (e.g., pramipexole, ropinirole)
- Catechol-O-methyl transferase (COMT) inhibitors (e.g., entacapone)
- Monoamine oxidase (MAO) B inhibitors (e.g., rasagiline, selegiline)

|                                                                                                                                                                                                                                                                     |                     |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name: Brand Apokyn, generic apomorphine hcl                                                                                                                                                                                                                 |                     |
| Approval Length                                                                                                                                                                                                                                                     | 12 month(s)         |
| Therapy Stage                                                                                                                                                                                                                                                       | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                                      | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p>1 - Documentation of positive clinical response to the requested therapy</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Patient will continue to receive treatment with a carbidopa/levodopa-containing medication</p> |                     |

## 2 . Revision History

| Date      | Notes                          |
|-----------|--------------------------------|
| 7/11/2023 | Updated T/F criteria language. |

Aqneursa



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-249190                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Guideline Name</b> | Aqneursa                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Michigan (ACUMI)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Pennsylvania (ACUPA)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 7/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                       |                       |
|-----------------------|-----------------------|
| Product Name:Aqneursa |                       |
| Approval Length       | 12 month(s)           |
| Therapy Stage         | Initial Authorization |

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Prior Authorization |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of Niemann-Pick disease type C (NPC)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Diagnosis has been genetically confirmed by mutation analysis of NPC1 and NPC2 genes</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Medication is being used to treat neurological manifestations of NPC</p> <p style="text-align: center;"><b>AND</b></p> <p><b>4</b> - ONE of the following:</p> <ul style="list-style-type: none"> <li>• Aqneursa is prescribed in combination with miglustat</li> <li>• Failure to miglustat as confirmed by claims history or submission of medical records</li> <li>• History of intolerance or contraindication to miglustat (please specify intolerance or contraindication)</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>5</b> - Medication is not being used in combination with Miplyffa (arimoclomol)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>6</b> - Medication is prescribed by or in consultation with a provider with expertise in the treatment of NPC</p> |                     |

|                       |             |
|-----------------------|-------------|
| Product Name:Aqneursa |             |
| Approval Length       | 12 month(s) |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                     |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of positive clinical response to Aqneursa therapy (e.g., slowed disease progression from baseline based on assessment with NPC–specific scales)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - ONE of the following:</p> <ul style="list-style-type: none"> <li>• Aqneursa is prescribed in combination with miglustat</li> <li>• Failure to miglustat as confirmed by claims history or submission of medical records</li> <li>• History of intolerance or contraindication to miglustat (please specify intolerance or contraindication)</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Medication is not being used in combination with Miplyffa (arimoclomol)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>4</b> - Medication is prescribed by or in consultation with a provider with expertise in the treatment of Niemann-Pick disease type C (NPC)</p> |                     |

## 2 . Revision History

| Date      | Notes                              |
|-----------|------------------------------------|
| 4/29/2025 | Updated formularies to add PA CAID |

Arcalyst



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-127433                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Guideline Name</b> | Arcalyst                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 8/1/2023 |
|-----------------|----------|

## 1 . Criteria

|                       |                                                |
|-----------------------|------------------------------------------------|
| Product Name:Arcalyst |                                                |
| Diagnosis             | Cryopyrin-Associated Periodic Syndromes (CAPS) |
| Approval Length       | 12 month(s)                                    |
| Therapy Stage         | Initial Authorization                          |
| Guideline Type        | Prior Authorization                            |

**Approval Criteria**

1 - Diagnosis of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS)

Product Name: Arcalyst

|                 |                                                        |
|-----------------|--------------------------------------------------------|
| Diagnosis       | Deficiency of Interleukin-1 Receptor Antagonist (DIRA) |
| Approval Length | 12 month(s)                                            |
| Therapy Stage   | Initial Authorization                                  |
| Guideline Type  | Prior Authorization                                    |

**Approval Criteria**

1 - Diagnosis of Deficiency of Interleukin-1 Receptor Antagonist (DIRA)

**AND**

2 - Disease is in remission (e.g., diary score of less than 0.5 [reflecting no fever, skin rash and bone pain], acute phase reactants [less than 0.5 mg/dL CRP (milligrams per deciliter C-Reactive protein)], absence of objective skin rash, no radiological evidence of active bone lesions)

Product Name: Arcalyst

|                 |                       |
|-----------------|-----------------------|
| Diagnosis       | Pericarditis          |
| Approval Length | 12 month(s)           |
| Therapy Stage   | Initial Authorization |
| Guideline Type  | Prior Authorization   |

**Approval Criteria**

1 - Diagnosis of recurrent pericarditis (RP)

|                                                                                                     |                                                                                                                      |
|-----------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------|
| Product Name:Arcalyst                                                                               |                                                                                                                      |
| Diagnosis                                                                                           | Cryopyrin-Associated Periodic Syndromes (CAPS), Deficiency of Interleukin-1 Receptor Antagonist (DIRA), Pericarditis |
| Approval Length                                                                                     | 12 month(s)                                                                                                          |
| Therapy Stage                                                                                       | Reauthorization                                                                                                      |
| Guideline Type                                                                                      | Prior Authorization                                                                                                  |
| <b>Approval Criteria</b><br><br>1 - Documentation of positive clinical response to Arcalyst therapy |                                                                                                                      |

## 2 . Revision History

| Date      | Notes                              |
|-----------|------------------------------------|
| 6/30/2023 | Removed RMH and ACUAZ formularies. |



Arikayce



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-217209                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Guideline Name</b> | Arikayce                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 5/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                       |                                                           |
|-----------------------|-----------------------------------------------------------|
| Product Name:Arikayce |                                                           |
| Diagnosis             | Refractory Mycobacterium avium complex (MAC) lung disease |
| Approval Length       | 6 month(s)                                                |
| Therapy Stage         | Initial Authorization                                     |
| Guideline Type        | Prior Authorization                                       |

### **Approval Criteria**

**1** - Diagnosis of refractory *Mycobacterium avium* complex (MAC) lung disease

**AND**

**2** - Submission of medical records (e.g., chart notes, laboratory values) documenting respiratory cultures positive for MAC within the previous 6 months

**AND**

**3** - Submission of medical records (e.g., chart notes, laboratory values) or prescription claims history documenting the patient has been receiving a multidrug background regimen containing at least TWO of the following agents for a minimum of 6 consecutive months within the past 12 months:

- Macrolide antibiotic (e.g., azithromycin, clarithromycin)
- Ethambutol
- Rifamycin antibiotic (e.g., rifampin, rifabutin)

**AND**

**4** - Patient will continue to receive a multidrug background regimen

**AND**

**5** - Documentation that the patient has NOT achieved negative sputum cultures after receipt of a multidrug background regimen for a minimum of 6 consecutive months

**AND**

**6** - In vitro susceptibility testing of recent (within 6 months) positive culture documents that the MAC isolate is susceptible to amikacin with a minimum inhibitory concentration (MIC) of less than or equal to 64 micrograms per milliliter (mcg/mL)

**AND**

**7** - Prescribed by or in consultation with **ONE** of the following:

- Infectious disease specialist
- Pulmonologist

**Product Name:**Arikayce

|                 |                                                           |
|-----------------|-----------------------------------------------------------|
| Diagnosis       | Refractory Mycobacterium avium complex (MAC) lung disease |
| Approval Length | 6 month(s)                                                |
| Therapy Stage   | Reauthorization                                           |
| Guideline Type  | Prior Authorization                                       |

**Approval Criteria**

**1** - **ONE** of the following:

**1.1** Documentation that the patient has achieved negative respiratory cultures

**OR**

**1.2** **ALL** of the following:

**1.2.1** Patient has **NOT** achieved negative respiratory cultures while on Arikayce

**AND**

**1.2.2** Physician attestation that patient has demonstrated clinical benefit while on Arikayce

**AND**

**1.2.3** In vitro susceptibility testing of most recent (within 6 months) positive culture with

available susceptibility testing documents that the Mycobacterium avium complex (MAC) isolate is susceptible to amikacin with a minimum inhibitory concentration (MIC) of less than 64 micrograms per milliliter (mcg/mL)

**AND**

**1.2.4** Patient has NOT received greater than 12 months of Arikayce therapy with continued positive respiratory cultures

**AND**

**2** - Submission of medical records (e.g., chart notes, laboratory values) or prescription claims history documenting that the patient continues to receive a multidrug background regimen containing at least TWO of the following agents:

- Macrolide antibiotic (e.g., azithromycin, clarithromycin)
- Ethambutol
- Rifamycin antibiotic (e.g., rifampin, rifabutin)

**AND**

**3** - Prescribed by or in consultation with ONE of the following:

- Infectious disease specialist
- Pulmonologist

## 2 . Revision History

| Date      | Notes                                         |
|-----------|-----------------------------------------------|
| 3/17/2025 | Combined formularies. Minor cosmetic updates. |

Atripla



## Prior Authorization Guideline

|                       |                                                                                                         |
|-----------------------|---------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-61025                                                                                                |
| <b>Guideline Name</b> | Atripla                                                                                                 |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>Medicaid - Community &amp; State New Jersey (PSI2300)</li> </ul> |

### Guideline Note:

|                    |          |
|--------------------|----------|
| Effective Date:    | 3/1/2020 |
| P&T Approval Date: |          |
| P&T Revision Date: |          |

## 1 . Criteria

|                                                                                     |                                    |
|-------------------------------------------------------------------------------------|------------------------------------|
| Product Name:Atripla                                                                |                                    |
| Diagnosis                                                                           | HIV (human immunodeficiency virus) |
| Approval Length                                                                     | 12 month(s)                        |
| Guideline Type                                                                      | Prior Authorization                |
| <b>Approval Criteria</b><br><br>1 - Diagnosis of HIV (human immunodeficiency virus) |                                    |

**AND**

**2** - One of the following:

**2.1** Patient is not an appropriate candidate for all of the following:

- Symfi or Symfi Lo (efavirenz/lamivudine/tenofovir disoproxil)
- Triumeq (abacavir/dolutegravir/lamivudine)
- Isentress/Isentress HD (raltegravir) plus Cimduo (lamivudine/tenofovir disoproxil)
- Tivicay (dolutegravir) plus Cimduo (lamivudine/tenofovir disoproxil)
- Juluca (dolutegravir/rilpivirine)

**OR**

**2.2** Patient is currently on Atripla therapy

|                                                                               |                           |
|-------------------------------------------------------------------------------|---------------------------|
| Product Name:Atripla                                                          |                           |
| Diagnosis                                                                     | Post-exposure prophylaxis |
| Approval Length                                                               | 4 Week(s)                 |
| Guideline Type                                                                | Prior Authorization       |
| <b>Approval Criteria</b><br><b>1</b> - Diagnosis of post-exposure prophylaxis |                           |

## 2 . Revision History

| Date      | Notes              |
|-----------|--------------------|
| 1/28/2020 | C&S Implementation |

Attruby



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-199189                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Guideline Name</b> | Attruby                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State Michigan (ACUMI)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania (ACUPA)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• </li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 4/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                      |             |
|----------------------|-------------|
| Product Name:Attruby |             |
| Approval Length      | 12 month(s) |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                       |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1 - Diagnosis of transthyretin (ATTR)-mediated amyloidosis with cardiomyopathy (ATTR-CM)</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>2 - One of the following:</b></p> <p><b>2.1</b> Documentation that the patient has a pathogenic TTR mutation (e.g., V30M)</p> <p style="text-align: center;"><b>OR</b></p> <p><b>2.2</b> Cardiac or noncardiac tissue biopsy demonstrating histologic confirmation of ATTR amyloid deposits</p> <p style="text-align: center;"><b>OR</b></p> <p><b>2.3</b> All of the following:</p> <ul style="list-style-type: none"> <li>• Echocardiogram or cardiac magnetic resonance imaging suggestive of amyloidosis</li> <li>• Radionuclide imaging (99mTc-DPD, 99mTc-PYP, or 99m Tc-HMDP) showing grade 2 or 3 cardiac uptake*</li> <li>• Absence of light chain amyloidosis</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>3 - Patient has New York Heart Association (NYHA) Functional Class I, II, or III heart failure</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>4 - Physician attests that the patient has an N-terminal pro-B-type natriuretic peptide (NT-proBNP) level that, when combined with signs and symptoms, is considered definitive for a diagnosis of ATTR-CM</b></p> |                       |



**AND**

**5** - One of the following:

- History of heart failure, with at least one prior hospitalization for heart failure
- Presence of signs and symptoms of heart failure (e.g., dyspnea, edema)

**AND**

**6** - Prescribed by or in consultation with a cardiologist

**AND**

**7** - Patient is not receiving Attruby in combination with an RNA-targeted therapy for ATTR amyloidosis [i.e., Amvuttra (vutrisiran), Onpattro (patisiran), Tegsedi (inotersen), Vyndaqel/Vyndamax (tafamadis), or Wainua (eplontersen)]

Notes

\*May require prior authorization and notification

Product Name:Attruby

Approval Length

12 month(s)

Therapy Stage

Reauthorization

Guideline Type

Prior Authorization

### Approval Criteria

**1** - Documentation that the patient has experienced a positive clinical response to Attruby (e.g., improved symptoms, quality of life, slowing of disease progression, decreased hospitalizations, etc.)

**AND**

**2** - Documentation that patient continues to have New York Heart Association (NYHA) Functional Class I, II, or III heart failure

**AND**

**3** - Prescribed by or in consultation with a cardiologist

**AND**

**4** - Patient is not receiving Attruby in combination with an RNA-targeted therapy for ATTR amyloidosis [i.e., Amvuttra (vutrisiran), Onpattro (patisiran), Tegsedi (inotersen), Vyndaqel/Vyndamax (tafamadis), or Wainua (eplontersen)]

## 2 . Revision History

| Date      | Notes                                                         |
|-----------|---------------------------------------------------------------|
| 2/25/2025 | Updated formularies in scope. No change to clinical criteria. |

Augtyro



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-400238                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Guideline Name</b> | Augtyro                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Washington (ACUWA, ACUWAAHE, ACUWAC)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 11/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                       |                                    |
|-----------------------|------------------------------------|
| Product Name: Augtyro |                                    |
| Diagnosis             | Non-Small Cell Lung Cancer (NSCLC) |
| Approval Length       | 12 month(s)                        |

|                                                                                                                                                                                                                                                                                                                                                                                |                       |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                  | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                 | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of non-small cell lung cancer (NSCLC)</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Disease is ONE of the following:</p> <ul style="list-style-type: none"> <li>• Advanced</li> <li>• Metastatic</li> <li>• Recurrent</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p>3 - Disease is ROS1-positive</p> |                       |

|                                                                                                                                                                                                                                                                  |                       |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Augtyro                                                                                                                                                                                                                                             |                       |
| Diagnosis                                                                                                                                                                                                                                                        | Solid Tumors          |
| Approval Length                                                                                                                                                                                                                                                  | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                    | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                   | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Presence of solid tumor(s)</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Disease is positive for neurotrophic tyrosine receptor kinase (NTRK) gene fusion (e.g., ETV6-NTRK3, TPM3-NTRK1, LMNA-NTRK1, etc.)</p> |                       |

**AND**

**3** - Disease is ONE of the following:

- Locally advanced
- Metastatic
- Unresectable

**Product Name:**Augtyro

|                 |                                                  |
|-----------------|--------------------------------------------------|
| Diagnosis       | Non-Small Cell Lung Cancer (NSCLC), Solid Tumors |
| Approval Length | 12 month(s)                                      |
| Therapy Stage   | Reauthorization                                  |
| Guideline Type  | Prior Authorization                              |

**Approval Criteria**

**1** - Patient does not show evidence of progressive disease while on Augtyro therapy

**Product Name:**Augtyro

|                 |                           |
|-----------------|---------------------------|
| Diagnosis       | NCCN Recommended Regimens |
| Approval Length | 12 month(s)               |
| Therapy Stage   | Initial Authorization     |
| Guideline Type  | Prior Authorization       |

**Approval Criteria**

**1** - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

**Product Name:**Augtyro

|                                                                                                           |                           |
|-----------------------------------------------------------------------------------------------------------|---------------------------|
| Diagnosis                                                                                                 | NCCN Recommended Regimens |
| Approval Length                                                                                           | 12 month(s)               |
| Therapy Stage                                                                                             | Reauthorization           |
| Guideline Type                                                                                            | Prior Authorization       |
| <b>Approval Criteria</b><br><br><b>1</b> - Documentation of positive clinical response to Augtyro therapy |                           |

## 2 . Revision History

| Date      | Notes                                                                                                     |
|-----------|-----------------------------------------------------------------------------------------------------------|
| 9/23/2025 | Updated formularies. Updated GPIs to add 160mg caps. Updated NS CLC criteria to include recurrent disease |

Austedo, Austedo XR



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-242253                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Guideline Name</b> | Austedo, Austedo XR                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 7/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                                  |                       |
|----------------------------------|-----------------------|
| Product Name:Austedo, Austedo XR |                       |
| Diagnosis                        | Tardive Dyskinesia    |
| Approval Length                  | 12 month(s)           |
| Therapy Stage                    | Initial Authorization |
| Guideline Type                   | Prior Authorization   |

### Approval Criteria

1 - Diagnosis of moderate to severe tardive dyskinesia

**AND**

2 - ONE of the following:

- Patient has persistent symptoms of tardive dyskinesia despite a trial of dose reduction, tapering, or discontinuation of the offending medication
- Patient is not a candidate for a trial of dose reduction, tapering, or discontinuation of the offending medication

**AND**

3 - Prescribed by or in consultation with ONE of the following:

- Neurologist
- Psychiatrist

**AND**

4 - If the request is for Austedo XR, the prescriber has given a clinical reason or special circumstance why the patient is unable to use Austedo immediate release (please document reason/special circumstance)

|                                  |                                             |
|----------------------------------|---------------------------------------------|
| Product Name:Austedo, Austedo XR |                                             |
| Diagnosis                        | Chorea associated with Huntington's Disease |
| Approval Length                  | 12 month(s)                                 |
| Therapy Stage                    | Initial Authorization                       |
| Guideline Type                   | Prior Authorization                         |
| <b>Approval Criteria</b>         |                                             |



**1 - Diagnosis of chorea associated with Huntington's Disease**

**AND**

**2 - Prescribed by or in consultation with ONE of the following:**

- Neurologist
- Psychiatrist

**AND**

**3 - If the request is for Austedo XR, the prescriber has given a clinical reason or special circumstance why the patient is unable to use Austedo immediate release (please document reason/special circumstance)**

|                                                                                                   |                                                                 |
|---------------------------------------------------------------------------------------------------|-----------------------------------------------------------------|
| Product Name:Austedo, Austedo XR                                                                  |                                                                 |
| Diagnosis                                                                                         | Chorea associated with Huntington's Disease, Tardive Dyskinesia |
| Approval Length                                                                                   | 12 month(s)                                                     |
| Therapy Stage                                                                                     | Reauthorization                                                 |
| Guideline Type                                                                                    | Prior Authorization                                             |
| <b>Approval Criteria</b><br><br><b>1 - Documentation of positive clinical response to therapy</b> |                                                                 |

## 2 . Revision History

| Date      | Notes            |
|-----------|------------------|
| 4/23/2025 | Added Austedo XR |

Avmapki Fakzynja Co-Pack



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-459190                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Guideline Name</b> | Avmapki Fakzynja Co-Pack                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Washington (ACUWA, ACUWAAHE, ACUWAC)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 12/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                                       |                |
|---------------------------------------|----------------|
| Product Name:Avmapki Fakzynja Co-Pack |                |
| Diagnosis                             | Ovarian Cancer |
| Approval Length                       | 12 month(s)    |

|                                                                                                                                                                                                                                                                                               |                       |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                                                                                                                                                                                                                                 | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of recurrent low-grade serous ovarian cancer (LGSOC)</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Tumor is KRAS-mutated</p> <p style="text-align: center;"><b>AND</b></p> <p>3 - Patient has received prior systemic therapy</p> |                       |

|                                                                                                                   |                     |
|-------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Avmapki Fakzynja Co-Pack                                                                             |                     |
| Diagnosis                                                                                                         | Ovarian Cancer      |
| Approval Length                                                                                                   | 12 month(s)         |
| Therapy Stage                                                                                                     | Reauthorization     |
| Guideline Type                                                                                                    | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p>1 - Patient does not show evidence of progressive disease while on therapy</p> |                     |

|                                       |                           |
|---------------------------------------|---------------------------|
| Product Name:Avmapki Fakzynja Co-Pack |                           |
| Diagnosis                             | NCCN Recommended Regimens |
| Approval Length                       | 12 month(s)               |
| Therapy Stage                         | Initial Authorization     |
| Guideline Type                        | Prior Authorization       |

**Approval Criteria**

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

|                                                                                                   |                           |
|---------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Avmapki Fakzynja Co-Pack                                                             |                           |
| Diagnosis                                                                                         | NCCN Recommended Regimens |
| Approval Length                                                                                   | 12 month(s)               |
| Therapy Stage                                                                                     | Reauthorization           |
| Guideline Type                                                                                    | Prior Authorization       |
| <p><b>Approval Criteria</b></p> <p>1 - Documentation of positive clinical response to therapy</p> |                           |

## 2 . Revision History

| Date       | Notes                                                                 |
|------------|-----------------------------------------------------------------------|
| 11/19/2025 | Removed ACUMI from markets in scope. No changes to clinical criteria. |

Ayvakit



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-398225                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Guideline Name</b> | Ayvakit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 10/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                      |                                       |
|----------------------|---------------------------------------|
| Product Name:Ayvakit |                                       |
| Diagnosis            | Gastrointestinal Stromal Tumor (GIST) |
| Approval Length      | 12 month(s)                           |
| Therapy Stage        | Initial Authorization                 |

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Prior Authorization |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1 - Diagnosis of gastrointestinal stromal tumor (GIST)</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>2 - ONE of the following:</b></p> <p><b>2.1</b> Submission of medical records or claims history confirming patient has unresectable, recurrent, or metastatic disease after failure on approved therapies (e.g., imatinib, sunitinib, regorafenib, ripretinib)</p> <p style="text-align: center;"><b>OR</b></p> <p><b>2.2 BOTH of the following:</b></p> <p><b>2.2.1</b> Disease is ONE of the following:</p> <ul style="list-style-type: none"> <li>• Unresectable</li> <li>• Resectable with significant morbidity</li> <li>• Metastatic</li> <li>• Recurrent</li> <li>• Limited progression</li> <li>• Gross residual disease (R2 resection)</li> <li>• Residual disease with significant morbidity</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>2.2.2</b> Presence of a platelet-derived growth factor receptor alpha (PDGFRA) exon mutation, including 18 D842V mutation</p> |                     |

|                      |                            |
|----------------------|----------------------------|
| Product Name:Ayvakit |                            |
| Diagnosis            | Myeloid/Lymphoid Neoplasms |
| Approval Length      | 12 month(s)                |
| Therapy Stage        | Initial Authorization      |

| Guideline Type                                                                                                                                                                                                                                                                                                                                                            | Prior Authorization |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of myeloid/lymphoid neoplasms with eosinophilia</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Presence of a FIP1L1-PDGFRα (platelet-derived growth factor receptor alpha) rearrangement</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Presence of a PDGFRα D842V mutation</p> |                     |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                       |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name: Ayvakit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                       |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Systemic Mastocytosis |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of ONE of the following:</p> <ul style="list-style-type: none"> <li>• Advanced systemic mastocytosis</li> <li>• Aggressive systemic mastocytosis</li> <li>• Systemic mastocytosis with an associated hematological neoplasm</li> <li>• Mast cell leukemia</li> <li>• Indolent systemic mastocytosis</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Platelet count is greater than or equal to <math>50 \times 10^9/\text{liter}</math></p> |                       |

|                                                                                                                       |                                                                                          |
|-----------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------|
| Product Name:Ayvakit                                                                                                  |                                                                                          |
| Diagnosis                                                                                                             | Gastrointestinal Stromal Tumor (GIST), Myeloid/Lymphoid Neoplasms, Systemic Mastocytosis |
| Approval Length                                                                                                       | 12 month(s)                                                                              |
| Therapy Stage                                                                                                         | Reauthorization                                                                          |
| Guideline Type                                                                                                        | Prior Authorization                                                                      |
| <b>Approval Criteria</b><br><b>1</b> - Patient does not show evidence of progressive disease while on Ayvakit therapy |                                                                                          |

|                                                                                                                                            |                           |
|--------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Ayvakit                                                                                                                       |                           |
| Diagnosis                                                                                                                                  | NCCN Recommended Regimens |
| Approval Length                                                                                                                            | 12 month(s)               |
| Therapy Stage                                                                                                                              | Initial Authorization     |
| Guideline Type                                                                                                                             | Prior Authorization       |
| <b>Approval Criteria</b><br><b>1</b> - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium |                           |

|                          |                           |
|--------------------------|---------------------------|
| Product Name:Ayvakit     |                           |
| Diagnosis                | NCCN Recommended Regimens |
| Approval Length          | 12 month(s)               |
| Therapy Stage            | Reauthorization           |
| Guideline Type           | Prior Authorization       |
| <b>Approval Criteria</b> |                           |



1 - Documentation of positive clinical response to Ayvakit therapy

## 2 . Revision History

| Date      | Notes     |
|-----------|-----------|
| 9/17/2025 | Added IN. |

Azole Antifungals



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-228271                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Guideline Name</b> | Azole Antifungals                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 6/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                                                                      |                            |
|----------------------------------------------------------------------|----------------------------|
| Product Name: Brand Sporanox capsules, generic itraconazole capsules |                            |
| Diagnosis                                                            | Systemic Fungal Infections |
| Approval Length                                                      | 12 month(s)                |
| Guideline Type                                                       | Prior Authorization        |

### Approval Criteria

1 - Diagnosis of ONE of the following:

- Blastomycosis
- Histoplasmosis
- Aspergillosis

**OR**

2 - BOTH of the following:

2.1 Diagnosis of coccidioidomycosis

**AND**

2.2 ONE of the following:

2.2.1 Failure to fluconazole (generic Diflucan) as confirmed by claims history or submission of medical records

**OR**

2.2.2 History of contraindication, intolerance, or resistance to fluconazole (generic Diflucan) (please specify intolerance, contraindication, or resistance)

|                                                                      |                           |
|----------------------------------------------------------------------|---------------------------|
| Product Name: Brand Sporanox capsules, generic itraconazole capsules |                           |
| Diagnosis                                                            | Onychomycosis Fingernails |
| Approval Length                                                      | 2 month(s)                |
| Therapy Stage                                                        | Initial Authorization     |
| Guideline Type                                                       | Prior Authorization       |
| Approval Criteria                                                    |                           |

1 - Diagnosis of fingernail onychomycosis confirmed by ONE of the following:

- KOH (potassium hydroxide) test
- Fungal culture
- Nail biopsy

Product Name: Brand Sporanox capsules, generic itraconazole capsules

|           |                           |
|-----------|---------------------------|
| Diagnosis | Onychomycosis Fingernails |
|-----------|---------------------------|

|                 |            |
|-----------------|------------|
| Approval Length | 2 month(s) |
|-----------------|------------|

|               |                 |
|---------------|-----------------|
| Therapy Stage | Reauthorization |
|---------------|-----------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

#### Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name: Brand Sporanox capsules, generic itraconazole capsules

|           |                        |
|-----------|------------------------|
| Diagnosis | Onychomycosis Toenails |
|-----------|------------------------|

|                 |            |
|-----------------|------------|
| Approval Length | 3 month(s) |
|-----------------|------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

#### Approval Criteria

1 - Diagnosis of toenail onychomycosis confirmed by ONE of the following:

- KOH (potassium hydroxide) test
- Fungal culture
- Nail biopsy

Product Name: Brand Sporanox capsules, generic itraconazole capsules

|                                                                                                          |                        |
|----------------------------------------------------------------------------------------------------------|------------------------|
| Diagnosis                                                                                                | Onychomycosis Toenails |
| Approval Length                                                                                          | 3 month(s)             |
| Therapy Stage                                                                                            | Reauthorization        |
| Guideline Type                                                                                           | Prior Authorization    |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of positive clinical response to therapy</p> |                        |

|                                                                                                                                                                                        |                     |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name: Brand Sporanox oral solution, generic itraconazole oral solution                                                                                                         |                     |
| Approval Length                                                                                                                                                                        | 12 month(s)         |
| Guideline Type                                                                                                                                                                         | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p>1 - ONE of the following diagnoses:</p> <ul style="list-style-type: none"> <li>Oropharyngeal candidiasis</li> <li>Esophageal candidiasis</li> </ul> |                     |

|                                                                                                                                                                            |                     |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name: Brand Vfend tablets, generic voriconazole tablets                                                                                                            |                     |
| Approval Length                                                                                                                                                            | 12 month(s)         |
| Guideline Type                                                                                                                                                             | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of invasive aspergillosis</p> <p style="text-align: center;"><b>OR</b></p> <p><b>2</b> - ALL of the following:</p> |                     |

**2.1** Diagnosis of candidemia

**AND**

**2.2** Patient is non-neutropenic

**AND**

**2.3** ONE of the following:

**2.3.1** Failure to fluconazole (generic Diflucan) as confirmed by claims history or submission of medical records

**OR**

**2.3.2** History of contraindication, intolerance, or resistance to fluconazole (generic Diflucan) (please specify intolerance, contraindication, or resistance)

**OR**

**3** - BOTH of the following:

**3.1** ONE of the following diagnoses:

- Candida infection in the abdomen
- Candida infection in the kidney
- Candida infection in the bladder wall
- Candida infection in wounds
- Disseminated Candida infections in skin
- Esophageal candidiasis

**AND**

**3.2** ONE of the following:

**3.2.1** Failure to fluconazole (generic Diflucan) as confirmed by claims history or submission of medical records

**OR**

**3.2.2** History of contraindication, intolerance, or resistance to fluconazole (generic Diflucan) (please specify intolerance, contraindication, or resistance)

**OR**

**4** - Diagnosis of *Scedosporium apiospermum* infection (asexual form of *Pseudallescheria boydii*)

**OR**

**5** - Diagnosis of *Fusarium* spp. infection including *Fusarium solani*

**OR**

**6** - Diagnosis of *Exserohilum* species infection

Product Name: Brand Vfend susp, generic voriconazole susp

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

### Approval Criteria

**1** - ONE of the following:

**1.1** Diagnosis of invasive aspergillosis including *Aspergillus fumigatus*

**OR**

**1.2** ALL of the following:

**1.2.1** Diagnosis of Candidemia

**AND**

**1.2.2** Patient is non-neutropenic

**AND**

**1.2.3** ONE of the following:

**1.2.3.1** Failure to fluconazole (generic Diflucan) as confirmed by claims history or submission of medical records

**OR**

**1.2.3.2** History of contraindication, intolerance, or resistance to fluconazole (generic Diflucan) (please specify intolerance, contraindication, or resistance)

**OR**

**1.3** BOTH of the following:

**1.3.1** ONE of the following diagnoses:

- Candida infection in the abdomen
- Candida infection in the kidney
- Candida infection in the bladder wall
- Candida infection in wounds
- Disseminated Candida infections in skin
- Esophageal candidiasis

**AND**

**1.3.2** ONE of the following:

**1.3.2.1** Failure to fluconazole (generic Diflucan) as confirmed by claims history or submission of medical records



**OR**

**1.3.2.2** History of contraindication, intolerance, or resistance to fluconazole (generic Diflucan) (please specify intolerance, contraindication, or resistance)

**OR**

**1.4** Diagnosis of *Scedosporium apiospermum* infection (asexual form of *Pseudallescheria boydii*)

**OR**

**1.5** Diagnosis of *Fusarium* spp. infection including *Fusarium solani*

**OR**

**1.6** Diagnosis of *Exserohilum* species infection

**AND**

**2** - Physician has provided rationale for the patient needing to use voriconazole oral suspension instead of voriconazole tablets

|                                                                                                                                     |                                                  |
|-------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|
| Product Name: Brand Noxafil tablets, generic posaconazole tablets                                                                   |                                                  |
| Diagnosis                                                                                                                           | Prophylaxis of Aspergillus or Candida Infections |
| Approval Length                                                                                                                     | 12 month(s)                                      |
| Guideline Type                                                                                                                      | Prior Authorization                              |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Used as prophylaxis of invasive fungal infections caused by ONE of the following:</p> |                                                  |

- Aspergillus
- Candida

**AND**

**2** - ONE of the following conditions:

**2.1** Patient is at high risk of infections due to severe immunosuppression from ONE of the following conditions:

**2.1.1** Hematopoietic stem cell transplant (HSCT) with graft-versus-host disease (GVHD)

**OR**

**2.1.2** Hematologic malignancies with prolonged neutropenia from chemotherapy [e.g., acute myeloid leukemia (AML), myelodysplastic syndromes (MDS)]

**OR**

**2.2** Patient has a prior fungal infection requiring secondary prophylaxis

|                                                                                                                                                 |                                     |
|-------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|
| Product Name: Brand Noxafil tablets, generic posaconazole tablets                                                                               |                                     |
| Diagnosis                                                                                                                                       | Treatment of Invasive Aspergillosis |
| Approval Length                                                                                                                                 | 84 Day(s)                           |
| Guideline Type                                                                                                                                  | Prior Authorization                 |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of invasive aspergillosis</p> <p><b>AND</b></p> <p><b>2</b> - ONE of the following:</p> |                                     |

**2.1** Failure to voriconazole (generic Vfend) as confirmed by claims history or submission of medical records

**OR**

**2.2** History of contraindication, intolerance, or resistance to voriconazole (generic Vfend) (please specify intolerance, contraindication, or resistance)

Product Name: Brand Noxafil suspension, generic posaconazole suspension, Noxafil delayed release suspension packets

|                 |                                                  |
|-----------------|--------------------------------------------------|
| Diagnosis       | Prophylaxis of Aspergillus or Candida Infections |
| Approval Length | 12 month(s)                                      |
| Guideline Type  | Prior Authorization                              |

### Approval Criteria

**1** - Used as prophylaxis of invasive fungal infections caused by ONE of the following:

- Aspergillus
- Candida

**AND**

**2** - ONE of the following conditions:

**2.1** Patient is at high risk of infections due to severe immunosuppression from ONE of the following conditions:

**2.1.1** Hematopoietic stem cell transplant (HSCT) with graft-versus-host disease (GVHD)

**OR**

**2.1.2** Hematologic malignancies with prolonged neutropenia from chemotherapy [e.g., acute myeloid leukemia (AML), myelodysplastic syndromes (MDS)]

**OR**

**2.2** Patient has a prior fungal infection requiring secondary prophylaxis

|                                                                         |                                 |
|-------------------------------------------------------------------------|---------------------------------|
| Product Name: Brand Noxafil suspension, generic posaconazole suspension |                                 |
| Diagnosis                                                               | Oropharyngeal Candidiasis (OPC) |
| Approval Length                                                         | 12 month(s)                     |
| Guideline Type                                                          | Prior Authorization             |

**Approval Criteria**

**1** - Diagnosis of oropharyngeal candidiasis (OPC)

**AND**

**2** - ONE of the following:

**2.1** Failure to ONE of the following as confirmed by claims history or submission of medical records:

- Fluconazole (generic Diflucan)
- Itraconazole (generic Sporanox)

**OR**

**2.2** History of contraindication, intolerance, or resistance to BOTH of the following (please specify intolerance, contraindication, or resistance):

- Fluconazole (generic Diflucan)
- Itraconazole (generic Sporanox)

|                        |            |
|------------------------|------------|
| Product Name: Cresemba |            |
| Approval Length        | 3 month(s) |

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Prior Authorization |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p>1 - BOTH of the following:</p> <p>1.1 Diagnosis of invasive aspergillosis</p> <p style="text-align: center;"><b>AND</b></p> <p>1.2 ONE of the following:</p> <p>1.2.1 Failure to voriconazole (generic Vfend) as confirmed by claims history or submission of medical records</p> <p style="text-align: center;"><b>OR</b></p> <p>1.2.2 History of contraindication, intolerance, or resistance to voriconazole (generic Vfend) (please specify intolerance, contraindication, or resistance)</p> <p style="text-align: center;"><b>OR</b></p> <p>2 - Diagnosis of invasive mucormycosis</p> |                     |

|                                                                                                                                                                                             |                     |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Tolsura                                                                                                                                                                        |                     |
| Approval Length                                                                                                                                                                             | 3 month(s)          |
| Guideline Type                                                                                                                                                                              | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of ONE of the following fungal infections:</p> <ul style="list-style-type: none"> <li>• Blastomycosis</li> <li>• Histoplasmosis</li> </ul> |                     |

- Aspergillosis

**AND**

**2 - ONE of the following:**

**2.1** Failure to itraconazole capsules (generic Sporanox) as confirmed by claims history or submission of medical records

**OR**

**2.2** History of contraindication or intolerance to itraconazole capsules (generic Sporanox) (please specify intolerance or contraindication)

Product Name: Brand Sporanox capsules, generic itraconazole capsules, Brand Sporanox oral solution, generic itraconazole oral solution, Brand Vfend tablets, generic voriconazole tablets, Brand Vfend suspension, generic voriconazole suspension, Brand Noxafil tablets, generic posaconazole tablets, Brand Noxafil oral suspension, generic posaconazole oral suspension, Noxafil delayed release suspension packets, Cresemba, Tolsura

|                 |                                                                             |
|-----------------|-----------------------------------------------------------------------------|
| Diagnosis       | Infectious Diseases Society of America (IDSA) Recommended Regimens          |
| Approval Length | Based on provider and IDSA recommended treatment durations, up to 12 months |
| Guideline Type  | Prior Authorization                                                         |

### Approval Criteria

**1** - Use is recognized for treatment of the diagnosis by the Infectious Diseases Society of America (IDSA)

## 2 . Revision History

| Date | Notes |
|------|-------|
|------|-------|

|          |                                                                                                                                                                      |
|----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 4/2/2025 | Updated formularies. Updated GPIs. Removed wait period from Spor anox reauthorization section for onychomycosis infections. Updated Vfend criteria for aspergillosis |
|----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|

Balversa



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-363188                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Guideline Name</b> | Balversa                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 9/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                        |                       |
|------------------------|-----------------------|
| Product Name: Balversa |                       |
| Diagnosis              | Urothelial Carcinoma  |
| Approval Length        | 12 month(s)           |
| Therapy Stage          | Initial Authorization |



| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Prior Authorization |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1 - Diagnosis of urothelial carcinoma</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>2 - Disease is ONE of the following:</b></p> <ul style="list-style-type: none"> <li>Locally advanced</li> <li>Metastatic</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>3 - Presence of FGFR3 genetic alterations</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>4 - Disease has progressed on or after at least one line of prior systemic therapy [e.g., platinum-based chemotherapy (e.g., cisplatin, carboplatin), immune checkpoint inhibitor (e.g., pembrolizumab, nivolumab, avelumab)]</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>5 - ONE of the following:</b></p> <ul style="list-style-type: none"> <li>Patient has received prior systemic therapy containing an immune checkpoint inhibitor (e.g., pembrolizumab, nivolumab, avelumab)</li> <li>Patient is not eligible for immune checkpoint inhibitor therapy (e.g., pembrolizumab, nivolumab, avelumab)</li> </ul> |                     |

|                       |                      |
|-----------------------|----------------------|
| Product Name:Balversa |                      |
| Diagnosis             | Salivary Gland Tumor |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                       |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of salivary gland tumor</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Disease is ONE of the following:</p> <ul style="list-style-type: none"> <li>• Recurrent</li> <li>• Unresectable</li> <li>• Metastatic</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p>3 - Presence of FGFR genetic alterations</p> <p style="text-align: center;"><b>AND</b></p> <p>4 - Disease has progressed on or after at least one line of prior systemic therapy [e.g., platinum-based chemotherapy (e.g., cisplatin, carboplatin)]</p> |                       |

|                                 |                           |
|---------------------------------|---------------------------|
| Product Name:Balversa           |                           |
| Diagnosis                       | Pancreatic Adenocarcinoma |
| Approval Length                 | 12 month(s)               |
| Therapy Stage                   | Initial Authorization     |
| Guideline Type                  | Prior Authorization       |
| <p><b>Approval Criteria</b></p> |                           |

**1** - Diagnosis of pancreatic adenocarcinoma

**AND**

**2** - Disease is ONE of the following:

- Locally advanced
- Metastatic
- Recurrent

**AND**

**3** - Presence of FGFR genetic alterations

|                                                                                                                                                                                                                              |                            |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|
| Product Name:Balversa                                                                                                                                                                                                        |                            |
| Diagnosis                                                                                                                                                                                                                    | Non-Small Cell Lung Cancer |
| Approval Length                                                                                                                                                                                                              | 12 month(s)                |
| Therapy Stage                                                                                                                                                                                                                | Initial Authorization      |
| Guideline Type                                                                                                                                                                                                               | Prior Authorization        |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of non-small cell lung cancer</p> <p><b>AND</b></p> <p><b>2</b> - Disease is metastatic</p> <p><b>AND</b></p> <p><b>3</b> - Presence of FGFR genetic alterations</p> |                            |

|                                                                                                                                                                                                                                                                |                       |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Balversa                                                                                                                                                                                                                                          |                       |
| Diagnosis                                                                                                                                                                                                                                                      | Breast Cancer         |
| Approval Length                                                                                                                                                                                                                                                | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                  | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                 | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of invasive breast cancer</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Disease is metastatic</p> <p style="text-align: center;"><b>AND</b></p> <p>3 - Presence of FGFR1-3 genetic alterations</p> |                       |

|                                                                                                                                                                      |                       |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Balversa                                                                                                                                                |                       |
| Diagnosis                                                                                                                                                            | Cholangiocarcinoma    |
| Approval Length                                                                                                                                                      | 12 month(s)           |
| Therapy Stage                                                                                                                                                        | Initial Authorization |
| Guideline Type                                                                                                                                                       | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of cholangiocarcinoma</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Disease is ONE of the following:</p> |                       |

- Unresectable
- Metastatic

**AND**

**3** - Presence of FGFR2 genetic alterations

**AND**

**4** - Disease has progressed on or after BOTH of the following:

- Lytgobi (futibatinib)
- Pemazyre (pemigatinib)

| Product Name:Balversa                                                                                                  |                                                                                                                                      |
|------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------|
| Diagnosis                                                                                                              | Urothelial Carcinoma, Salivary Gland Tumor, Pancreatic Adenocarcinoma, Non-Small Cell Lung Cancer, Breast Cancer, Cholangiocarcinoma |
| Approval Length                                                                                                        | 12 month(s)                                                                                                                          |
| Therapy Stage                                                                                                          | Reauthorization                                                                                                                      |
| Guideline Type                                                                                                         | Prior Authorization                                                                                                                  |
| <b>Approval Criteria</b><br><b>1</b> - Patient does not show evidence of progressive disease while on Balversa therapy |                                                                                                                                      |

| Product Name:Balversa |                           |
|-----------------------|---------------------------|
| Diagnosis             | NCCN Recommended Regimens |
| Approval Length       | 12 month(s)               |
| Therapy Stage         | Initial Authorization     |
| Guideline Type        | Prior Authorization       |

**Approval Criteria**

1 - Use supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

|                                                                                                            |                           |
|------------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Balversa                                                                                      |                           |
| Diagnosis                                                                                                  | NCCN Recommended Regimens |
| Approval Length                                                                                            | 12 month(s)               |
| Therapy Stage                                                                                              | Reauthorization           |
| Guideline Type                                                                                             | Prior Authorization       |
| <p><b>Approval Criteria</b></p> <p>1 - Documentation of positive clinical response to Balversa therapy</p> |                           |

## 2 . Revision History

| Date      | Notes                         |
|-----------|-------------------------------|
| 8/11/2025 | Updated formularies to add IN |

Baxdela



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-219299                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Guideline Name</b> | Baxdela                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 5/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                      |                                        |
|----------------------|----------------------------------------|
| Product Name:Baxdela |                                        |
| Diagnosis            | Community-Acquired Bacterial Pneumonia |
| Approval Length      | 10 Day(s)                              |
| Guideline Type       | Prior Authorization                    |

### **Approval Criteria**

**1** - For continuation of therapy upon hospital discharge

**OR**

**2** - As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication

**OR**

**3** - All of the following:

**3.1** Diagnosis of community-acquired bacterial pneumonia (CABP)

**AND**

**3.2** Infection caused by an organism that is confirmed to be or likely to be susceptible to treatment with Baxdela

**AND**

**3.3** One of the following:

**3.3.1** Failure to three of the following antibiotics or antibiotic regimens as confirmed by claims history or submission of medical records:

- Amoxicillin
- A macrolide
- Doxycycline
- A fluoroquinolone
- Combination therapy with amoxicillin/clavulanate or cephalosporin AND a macrolide or doxycycline

**OR**



**3.3.2** History of intolerance or contraindication to all of the following antibiotics or antibiotic regimens (please specify intolerance or contraindication)

- Amoxicillin
- A macrolide
- Doxycycline
- A fluoroquinolone
- Combination therapy with amoxicillin/clavulanate or cephalosporin AND a macrolide or doxycycline

|                       |                                                    |
|-----------------------|----------------------------------------------------|
| Product Name: Baxdela |                                                    |
| Diagnosis             | Acute Bacterial Skin and Skin Structure Infections |
| Approval Length       | 14 Day(s)                                          |
| Guideline Type        | Prior Authorization                                |

**Approval Criteria**

1 - For continuation of therapy upon hospital discharge

**OR**

2 - As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication

**OR**

3 - All of the following:

3.1 One of the following diagnoses:

3.1.1 Both of the following

3.1.1.1 Acute bacterial skin and skin structure infections

**AND**

**3.1.1.2** Infection caused by methicillin-resistant *Staphylococcus aureus* (MRSA) documented by culture and sensitivity report

**OR**

**3.1.2** Both of the following:

**3.1.2.1** Empirical treatment of patients with acute bacterial skin and skin structure infections

**AND**

**3.1.2.2** Presence of MRSA infection is likely

**AND**

**3.2** ONE of the following:

**3.2.1** Failure of linezolid (generic Zyvox) confirmed by claims history or submitted medical records

**OR**

**3.2.2** History of intolerance or contraindication to linezolid (generic Zyvox) (please specify intolerance or contraindication)

**AND**

**3.3** One of the following:

**3.3.1** Failure to one of the following antibiotics as confirmed by claims history or submitted medical records:

- Sulfamethoxazole-trimethoprim (SMZ-TMP)
- A tetracycline
- Clindamycin

**OR**

**3.3.2** History of intolerance or contraindication to all of the following (please specify intolerance or contraindication):

- Sulfamethoxazole-trimethoprim (SMZ-TMP)
- A tetracycline
- Clindamycin

**OR**

**4** - All of the following:

**4.1** Diagnosis of acute bacterial skin and skin structure infections

**AND**

**4.2** Infection caused by an organism that is confirmed to be or likely to be susceptible to treatment with Baxdela

**AND**

**4.3** One of the following:

**4.3.1** Failure to three of the following antibiotics as confirmed by claims history or submitted medical records:

- A penicillin
- A cephalosporin
- A tetracycline
- Sulfamethoxazole-trimethoprim (SMZ-TMP)
- Clindamycin

**OR**

**4.3.2** History of intolerance or contraindication to all of the following antibiotics (please specify intolerance or contraindication):

- A penicillin

- A cephalosporin
- A tetracycline
- Sulfamethoxazole-trimethoprim (SMZ-TMP)
- Clindamycin

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                             |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| Product Name: Baxdela                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                             |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Off-Label Uses                                                              |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Based on provider and IDSA recommended treatment durations, up to 6 months. |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Prior Authorization                                                         |
| <p><b>Approval Criteria</b></p> <p>1 - For continuation of therapy upon hospital discharge</p> <p style="text-align: center;"><b>OR</b></p> <p>2 - As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication</p> <p style="text-align: center;"><b>OR</b></p> <p>3 - The drug has been recognized for treatment of the indication by the Infectious Diseases Society of America (IDSA)</p> |                                                                             |

## 2 . Revision History

| Date      | Notes               |
|-----------|---------------------|
| 3/19/2025 | Updated formularies |

Belbuca\_Butrans



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                               |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-161143                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Guideline Name</b> | Belbuca_Butrans                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 1/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                                                                         |                                                                                                       |
|-------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------|
| Product Name:Belbuca, generic buprenorphine patches, Brand Butrans      |                                                                                                       |
| Diagnosis                                                               | DUR: Opioid Naïve (Not having filled an opioid in the past 60 days) exceeding the 7 day supply limit* |
| Guideline Type                                                          | Prior Authorization                                                                                   |
| <b>Approval Criteria</b><br><br>1 - Patient meets ONE of the following: |                                                                                                       |

- Cancer-related pain (i.e., patients undergoing active cancer treatment; or cancer survivors with chronic pain who have completed cancer treatment, are in clinical remission, or are under cancer surveillance)
- End of life care, including hospice care
- Palliative care
- Sickle cell anemia

**OR**

**2** - Prescriber attests that the patient has received an opioid within the past 60 days

|       |                                                                                                                                                                                                                   |
|-------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Notes | *Approval length for cancer related pain, end of life, palliative care, or sickle cell pain will be issued for 12 months. All other approvals will be issued for the requested duration, not to exceed one month. |
|-------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

**Product Name:**Belbuca, generic buprenorphine patches, Brand Butrans

|                 |                                                                         |
|-----------------|-------------------------------------------------------------------------|
| Diagnosis       | Cancer-related pain/Hospice/Sickle Cell Anemia/End of Life related pain |
| Approval Length | 12 month(s)                                                             |
| Guideline Type  | Prior Authorization                                                     |

### Approval Criteria

**1** - The patient is being treated for one of the following:

- Cancer-related pain (i.e., patients undergoing active cancer treatment; or cancer survivors with chronic pain who have completed cancer treatment, are in clinical remission, or are under cancer surveillance)
- Hospice
- Sickle cell anemia
- End of life related pain

**AND**

**2** - If the request is for Belbuca or Brand Butrans, the prescriber provides a reason or special circumstance the patient cannot use generic buprenorphine patches

|       |                                                                                                                                                  |
|-------|--------------------------------------------------------------------------------------------------------------------------------------------------|
| Notes | If the patient is currently taking the requested long-acting opioid for at least 30 days and does not meet the medical necessity authorization c |
|-------|--------------------------------------------------------------------------------------------------------------------------------------------------|

|  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|--|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | <p>riteria requirements for treatment with an opioid, a denial should be issued and a maximum 60-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment.</p> <p>If the patient is currently taking the requested long-acting opioid for at least 30 days and has met the medical necessity authorization criteria requirements for treatment with an opioid, but has not tried generic buprenorphine patches, a denial should be issued and a maximum 60-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment. Additionally, a 12-month authorization should be entered for generic buprenorphine patches.</p> |
|--|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------|
| Product Name:Belbuca, generic buprenorphine patches, Brand Butrans                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                           |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Non-cancer related pain/Non-hospice/Non-sickle cell anemia pain/Non-end of life care pain |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 6 month(s)                                                                                |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Initial Authorization                                                                     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Prior Authorization                                                                       |
| <p><b>Approval Criteria</b></p> <p><b>1 - Prescriber attests to BOTH of the following:</b></p> <p><b>1.1 Patient has been screened for substance abuse/opioid dependence</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>1.2 Pain is moderate to severe and expected to persist for an extended period of time (chronic)</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>2 - Treatment goals are defined and include estimated duration of treatment (must document treatment goals)</b></p> |                                                                                           |

**AND**

**3 - BOTH of the following:**

**3.1** Patient has been screened for underlying depression and/or anxiety

**AND**

**3.2** If applicable, any underlying conditions have been or will be addressed

**AND**

**4 - ONE of the following:**

**4.1** The patient has a history of failure to a trial of tramadol IR (immediate release) as confirmed by claims history or submission of medical records

**OR**

**4.2** The patient has a contraindication or intolerance to tramadol IR (please specify contraindication or intolerance)

**OR**

**4.3** The patient is already receiving chronic opioid therapy prior to surgery for postoperative pain, or if the postoperative pain is expected to be moderate to severe and persist for an extended period of time

**OR**

**4.4** Patient is new to plan and currently established on Belbuca or Butrans for at least the past 30 days

**AND**



**5** - If the request is for neuropathic pain (examples of neuropathic pain include neuralgias and neuropathies), BOTH of the following:

**5.1** Unless it is contraindicated, the patient has not exhibited an adequate response to 8 weeks of treatment with gabapentin titrated to a therapeutic dose (document date of trial) (if contraindicated, document contraindication)

**AND**

**5.2** Unless it is contraindicated, the patient has not exhibited an adequate response to at least 6 weeks of treatment with a tricyclic antidepressant titrated to the maximum tolerated dose (document drug and date of trial) (if contraindicated, document contraindication)

**AND**

**6** - If the request is for Belbuca or Brand Butrans, the prescriber provides a reason or special circumstance the patient cannot use generic buprenorphine patches

|       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|-------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Notes | <p>If the patient is currently taking the requested long-acting opioid for at least 30 days and does not meet the medical necessity authorization criteria requirements for treatment with an opioid, a denial should be issued and a maximum 60-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment.</p> <p>If the patient is currently taking the requested long-acting opioid for at least 30 days and has met the medical necessity authorization criteria requirements for treatment with an opioid, but has not tried generic buprenorphine patches, a denial should be issued and a maximum 60-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment. Additionally, a 6 month authorization should be entered for generic buprenorphine patches.</p> |
|-------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                                                                     |                                                                                           |
|---------------------------------------------------------------------|-------------------------------------------------------------------------------------------|
| Product Name: Belbuca, generic buprenorphine patches, Brand Butrans |                                                                                           |
| Diagnosis                                                           | Non-cancer related pain/Non-hospice/Non-sickle cell anemia pain/Non-end of life care pain |
| Approval Length                                                     | 6 month(s)                                                                                |
| Therapy Stage                                                       | Reauthorization                                                                           |
| Guideline Type                                                      | Prior Authorization                                                                       |

### Approval Criteria

**1** - Documented meaningful improvement in pain and function when assessed against treatment goals (document improvement in function or pain score improvement)

**AND**

**2** - Documented rationale for not tapering and discontinuing opioid if treatment goals are not being met

**AND**

**3** - Prescriber attests to BOTH of the following:

**3.1** Patient has been screened for substance abuse/opioid dependence

**AND**

**3.2** Pain is moderate to severe and expected to persist for an extended period of time (chronic)

**AND**

**4** - If the request is for Belbuca or Brand Butrans, the prescriber provides a reason or special circumstance the patient cannot use generic buprenorphine patches

|       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|-------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Notes | <p>If the patient is currently taking the requested long-acting opioid for at least 30 days and does not meet the medical necessity authorization criteria requirements for treatment with an opioid, a denial should be issued and a maximum 60-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment.</p> <p>If the patient is currently taking the requested long-acting opioid for at least 30 days and has met the medical necessity authorization criteria requirements for treatment with an opioid, but has not tried generic buprenorphine patches, a denial should be issued and a maximum 60-day authorization may be authorized one time for the requested drug/st</p> |
|-------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|  |                                                                                                                                                                                        |
|--|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | length combination up to the requested quantity for transition to an alternative treatment. Additionally, a 6 month authorization should be entered for generic buprenorphine patches. |
|--|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                 |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Product Name:Belbuca, generic buprenorphine patches, Brand Butrans                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                 |
| Guideline Type                                                                                                                                                                                                                                                                                                             | Quantity Limit                                                                                                                                                                                                                                                  |
| <p><b>Approval Criteria</b></p> <p>1 - The requested dose cannot be achieved by moving to a higher strength of the product</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - The requested dose is within the FDA (Food and Drug Administration) maximum dose per day, where an FDA maximum dose per day exists</p> |                                                                                                                                                                                                                                                                 |
| Notes                                                                                                                                                                                                                                                                                                                      | <p>Approval durations:</p> <p>12 months for cancer related pain/hospice/sickle cell anemia related pain/end of life related pain.</p> <p>6 months for non-cancer related pain/non-hospice/non-sickle cell anemia related pain/non-end of life related pain.</p> |

|                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                      |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|
| Product Name:Belbuca, generic buprenorphine patches, Brand Butrans                                                                                                                                                                                                                                                                                                                                           |                                                                                      |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                    | Cancer-related pain/Hospice/End of Life Related Pain/Sickle Cell Anemia Related Pain |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                              | 12 month(s)                                                                          |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                               | Morphine Milligram Equivalents (MME)                                                 |
| <p><b>Approval Criteria</b></p> <p>1 - Patient has one of the following:</p> <ul style="list-style-type: none"> <li>• Cancer-related pain (i.e., patients undergoing active cancer treatment; or cancer survivors with chronic pain who have completed cancer treatment, are in clinical remission, or are under cancer surveillance)</li> <li>• Hospice pain</li> <li>• An end of life diagnosis</li> </ul> |                                                                                      |

|                                                                                   |                                                                                                                                           |
|-----------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"> <li>Sickle cell anemia related pain</li> </ul> |                                                                                                                                           |
| Notes                                                                             | The authorization should be entered for an MME of 9999 so as to prevent future disruptions in therapy if the patient's dose is increased. |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                      |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------|
| Product Name: Belbuca, generic buprenorphine patches, Brand Butrans                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                      |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Non-cancer related pain/Non-hospice/Non-End of Life Related Pain/Non-Sickle Cell Anemia Related Pain |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 6 month(s)                                                                                           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Initial Authorization                                                                                |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Morphine Milligram Equivalents (MME)                                                                 |
| <p><b>Approval Criteria</b></p> <p>1 - Prescriber attests that the patient has been screened for substance abuse/opioid dependence</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Treatment goals are defined and include estimated duration of treatment (must document treatment goals)</p> <p style="text-align: center;"><b>AND</b></p> <p>3 - BOTH of the following:</p> <p>3.1 Patient has been screened for underlying depression and/or anxiety</p> <p style="text-align: center;"><b>AND</b></p> <p>3.2 If applicable, any underlying conditions have been or will be addressed</p> <p style="text-align: center;"><b>AND</b></p> |                                                                                                      |

**4 - ONE of the following:**

**4.1** Opioid medication doses of less than 90 MME (Morphine Milligram Equivalents) have been tried and did not adequately control pain (document drug regimen or MME and dates of therapy)

**OR**

**4.2** Patient is new to plan and currently established on the requested MME for at least the past 30 days

|       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|-------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Notes | <p>Authorization will be issued for 6 months for non-cancer related pain/n on-hospice/non-sickle cell anemia related pain/non-end of life related pain up to the current requested MME plus 90 MME.</p> <p>If the patient has been established on the requested MME dose for at least 30 days and does not meet the medical necessity authorization criteria requirements, a denial should be issued and a maximum 60-day authorization may be authorized one time for the requested MME dose.</p> |
|-------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

**Product Name:**Belbuca, generic buprenorphine patches, Brand Butrans

|                 |                                                                                                 |
|-----------------|-------------------------------------------------------------------------------------------------|
| Diagnosis       | Non-cancer related/Non-hospice/Non-End of Life Related Pain/Non-Sickle Cell Anemia Related Pain |
| Approval Length | 6 month(s)                                                                                      |
| Therapy Stage   | Reauthorization                                                                                 |
| Guideline Type  | Morphine Milligram Equivalents (MME)                                                            |

**Approval Criteria**

**1** - Prescriber attests that the patient has been screened for substance abuse/opioid dependence

**AND**

**2** - Documented rationale for not tapering and discontinuing opioid if treatment goals are not being met

|                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>AND</b>                                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>3</b> - Documented meaningful improvement in pain and function when assessed against treatment goals (document improvement in function or pain score improvement) |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Notes                                                                                                                                                                | <p>Authorization will be issued for 6 months for non-cancer related pain/non-hospice/non-sickle cell anemia related pain/non-end of life related pain up to the current requested MME plus 90 MME</p> <p>If the patient has been established on the requested MME dose for at least 30 days and does not meet the medical necessity authorization criteria requirements, a denial should be issued and a maximum 60-day authorization may be authorized one time for the requested MME dose.</p> |

## 2 . Revision History

| Date       | Notes                                                       |
|------------|-------------------------------------------------------------|
| 11/21/2024 | Updated language to clarify "cancer" is Cancer-related pain |

Benlysta



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-373479                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Guideline Name</b> | Benlysta                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 10/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                           |                              |
|---------------------------|------------------------------|
| Product Name: Benlysta SQ |                              |
| Diagnosis                 | Systemic Lupus Erythematosus |
| Approval Length           | 12 month(s)                  |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                       |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of systemic lupus erythematosus</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Patient is currently receiving standard immunosuppressive therapy [e.g., hydroxychloroquine, chloroquine, prednisone, azathioprine, methotrexate]</p> <p style="text-align: center;"><b>AND</b></p> <p>3 - Patient does NOT have severe active central nervous system lupus</p> <p style="text-align: center;"><b>AND</b></p> <p>4 - Patient is NOT receiving Benlysta in combination with any of the following:</p> <ul style="list-style-type: none"> <li>Targeted Immunomodulator [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Kineret (anakinra)]</li> <li>Lupkynis (voclosporin)</li> <li>Saphnelo (anifrolumab-fnia)</li> </ul> |                       |

|                                 |                        |
|---------------------------------|------------------------|
| Product Name: Benlysta SQ       |                        |
| Diagnosis                       | Active Lupus Nephritis |
| Approval Length                 | 12 month(s)            |
| Therapy Stage                   | Initial Authorization  |
| Guideline Type                  | Prior Authorization    |
| <p><b>Approval Criteria</b></p> |                        |



**1 - Diagnosis of active lupus nephritis**

**AND**

**2 - Patient is currently receiving standard immunosuppressive therapy for systemic lupus erythematosus [e.g., hydroxychloroquine, chloroquine, prednisone, azathioprine, methotrexate]**

**AND**

**3 - Patient does NOT have severe active central nervous system lupus**

**AND**

**4 - Patient is NOT receiving Benlysta in combination with any of the following:**

- Targeted Immunomodulator [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Kineret (anakinra)]
- Lupkynis (voclosporin)
- Saphnelo (anifrolumab-fnia)

**Product Name: Benlysta SQ**

|                 |                                                      |
|-----------------|------------------------------------------------------|
| Diagnosis       | Systemic Lupus Erythematosus, Active Lupus Nephritis |
| Approval Length | 12 month(s)                                          |
| Therapy Stage   | Reauthorization                                      |
| Guideline Type  | Prior Authorization                                  |

**Approval Criteria**

**1 - Documentation of positive clinical response to Benlysta therapy**

**AND**

**2** - Patient is NOT receiving Benlysta in combination with any of the following:

- Targeted Immunomodulator [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Kineret (anakinra)]
- Lupkynis (voclosporin)
- Saphnelo (anifrolumab-fnia)

## 2 . Revision History

| Date      | Notes                                                  |
|-----------|--------------------------------------------------------|
| 8/26/2025 | Combined formularies. No changes to clinical criteria. |

Berinert



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-249325                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Guideline Name</b> | Berinert                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 7/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                        |                       |
|------------------------|-----------------------|
| Product Name: Berinert |                       |
| Approval Length        | 12 month(s)           |
| Therapy Stage          | Initial Authorization |
| Guideline Type         | Prior Authorization   |

### **Approval Criteria**

**1** - Diagnosis of hereditary angioedema (HAE) as confirmed by ONE of the following:

**1.1** C1 inhibitor (C1-INH) deficiency or dysfunction (Type I or II HAE) as documented by ONE of the following (per laboratory standard):

- C1-INH antigenic level below the lower limit of normal
- C1-INH functional level below the lower limit of normal

**OR**

**1.2** HAE with normal C1 inhibitor levels and ONE of the following:

- Confirmed presence of variant(s) in the gene(s) for factor XII, angiotensin-converting enzyme 1, plasminogen-1, kininogen-1, myoferlin, or heparan sulfate-glucosaminase 3-O-sulfotransferase 6
- Recurring angioedema attacks that are refractory to high-dose antihistamines with confirmed family history of angioedema
- Recurring angioedema attacks that are refractory to high-dose antihistamines with unknown background de-novo mutation(s) (i.e., no family history) (HAE-unknown)

**AND**

**2** - Prescribed for the acute treatment of HAE attacks

**AND**

**3** - Not used in combination with other products indicated for the acute treatment of HAE attacks (e.g., Firazyr, Ruconest)

**AND**

**4** - ONE of the following:

**4.1** Failure of Ruconest as confirmed by claims history or submission of medical records

**OR**

**4.2** History of intolerance or contraindication to Ruconest (please specific intolerance or contraindication)

**OR**

**4.3** Patient is currently on Berinert therapy as confirmed by claims history or submission of medical records

**AND**

**5** - Prescribed by ONE of the following:

- Immunologist
- Allergist

|                                                                                                                                                                                                                                                                                                           |                     |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name: Berinert                                                                                                                                                                                                                                                                                    |                     |
| Approval Length                                                                                                                                                                                                                                                                                           | 12 month(s)         |
| Therapy Stage                                                                                                                                                                                                                                                                                             | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                                                                            | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of positive clinical response to Berinert therapy</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Prescribed for the acute treatment of HAE (hereditary angioedema) attacks</p> <p style="text-align: center;"><b>AND</b></p> |                     |

**3** - Not used in combination with other products indicated for the acute treatment of HAE attacks (e.g., Firazyr, Ruconest)

**AND**

**4** - Prescribed by ONE of the following:

- Immunologist
- Allergist

## 2 . Revision History

| Date     | Notes                                                  |
|----------|--------------------------------------------------------|
| 5/1/2025 | Combined formularies. No changes to clinical criteria. |

Besremi



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-159211                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Guideline Name</b> | Besremi                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>•</li> <li>•</li> <li>•</li> <li>•</li> <li>•</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 1/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                      |                   |
|----------------------|-------------------|
| Product Name:Besremi |                   |
| Diagnosis            | Polycythemia Vera |
| Approval Length      | 12 month(s)       |

|                                                                       |                     |
|-----------------------------------------------------------------------|---------------------|
| Guideline Type                                                        | Prior Authorization |
| <b>Approval Criteria</b><br><b>1 - Diagnosis of polycythemia vera</b> |                     |

|                                                                                                                                            |                           |
|--------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Besremi                                                                                                                       |                           |
| Diagnosis                                                                                                                                  | NCCN Recommended Regimens |
| Approval Length                                                                                                                            | 12 month(s)               |
| Therapy Stage                                                                                                                              | Initial Authorization     |
| Guideline Type                                                                                                                             | Prior Authorization       |
| <b>Approval Criteria</b><br><b>1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium</b> |                           |

|                                                                                                       |                           |
|-------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Besremi                                                                                  |                           |
| Diagnosis                                                                                             | NCCN Recommended Regimens |
| Approval Length                                                                                       | 12 month(s)               |
| Therapy Stage                                                                                         | Reauthorization           |
| Guideline Type                                                                                        | Prior Authorization       |
| <b>Approval Criteria</b><br><b>1 - Documentation of positive clinical response to Besremi therapy</b> |                           |

## 2 . Revision History

|      |       |
|------|-------|
| Date | Notes |
|------|-------|



|           |             |
|-----------|-------------|
| 11/4/2024 | New program |
|-----------|-------------|

Biltricide



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-228208                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Guideline Name</b> | Biltricide                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Arizona (ACUAZ, ACUAZEC)</li> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania (ACUPA)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Washington (ACUWA, ACUWAAHE, ACUWAC)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 5/1/2025 |
|-----------------|----------|

## 1 . Criteria

Product Name: Brand Biltricide, generic praziquantel

|                                                                                                                                                                                                                                                                                                                             |                     |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Approval Length                                                                                                                                                                                                                                                                                                             | 12 month(s)         |
| Guideline Type                                                                                                                                                                                                                                                                                                              | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1 - ONE of the following:</b></p> <p><b>1.1</b> Infections due to schistosoma</p> <p style="text-align: center;"><b>OR</b></p> <p><b>1.2</b> Infections due to the liver trematodes (flukes), Clonorchis sinensis/Opisthorchis viverrini (i.e., clonorchiasis or opisthorchiasis)</p> |                     |

## 2 . Revision History

| Date      | Notes               |
|-----------|---------------------|
| 3/26/2025 | Updated formularies |

Bimzelx



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-173201                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Guideline Name</b> | Bimzelx                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 4/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                      |                        |
|----------------------|------------------------|
| Product Name:Bimzelx |                        |
| Diagnosis            | Plaque Psoriasis (PsO) |
| Approval Length      | 12 month(s)            |
| Therapy Stage        | Initial Authorization  |
| Guideline Type       | Prior Authorization    |

## **Approval Criteria**

**1** - ALL of the following:

**1.1** Diagnosis of moderate to severe plaque psoriasis

**AND**

**1.2** ONE of the following:

**1.2.1** ALL of the following:

**1.2.1.1** Greater than or equal to 3% body surface area involvement, palmoplantar, facial, genital involvement, or severe scalp psoriasis

**AND**

**1.2.1.2** ONE of the following:

**1.2.1.2.1** Failure of ONE of the following topical therapy classes confirmed by claims history or submitted medical records:

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin
- Coal tar

**OR**

**1.2.1.2.2** History of intolerance or contraindication to ALL of the following topical therapy classes (please specify intolerance or contraindication):

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin

- Coal tar

**AND**

**1.2.1.3** ONE of the following:

- Failure of a 3 month trial of methotrexate, at the maximally indicated doses, confirmed by claims history or submitted medical records
- History of intolerance or contraindication to methotrexate (please specify intolerance or contraindication)

**OR**

**1.2.2** Patient has been previously treated with a targeted immunomodulator FDA (Food and Drug Administration)-approved for the treatment of plaque psoriasis as confirmed by claims history or submission of medical records [e.g., Enbrel (etanercept), Cimzia (certolizumab), adalimumab, Orencia (abatacept), Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Ilumya (tildrakizumab), Otezla (apremilast), ustekinumab]

**AND**

**1.3** Patient is not receiving Bimzelx in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast), ustekinumab]

**AND**

**1.4** ONE of the following:

**1.4.1** Failure to two of the following preferred products confirmed by claims history or submitted medical records:

- One of the preferred adalimumab products\*
- Enbrel (etanercept)
- One of the preferred ustekinumab products\*

**OR**

**1.4.2** History of intolerance or contraindication to ALL of the following preferred products (please specify intolerance or contraindication):

- One of the preferred adalimumab products\*
- Enbrel (etanercept)
- One of the preferred ustekinumab products\*

**AND**

**1.5** ONE of the following:

- Failure to Cosentyx (secukinumab) confirmed by claims history or submitted medical records
- History of intolerance or contraindication to Cosentyx (secukinumab) (please specify intolerance or contraindication)

**AND**

**1.6** Prescribed by or in consultation with a dermatologist

**OR**

**2** - ALL of the following:

**2.1** Patient is currently on Bimzelx therapy as confirmed by claims history or submission of medical records

**AND**

**2.2** Diagnosis of moderate to severe plaque psoriasis

**AND**

**2.3** Patient is not receiving Bimzelx in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept),

adalimumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast), ustekinumab]

**AND**

**2.4 Prescribed by or in consultation with a dermatologist**

|       |                              |
|-------|------------------------------|
| Notes | *See PDL links in Background |
|-------|------------------------------|

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Bimzelx                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                           |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Psoriatic Arthritis (PsA) |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | 12 month(s)               |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Initial Authorization     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Prior Authorization       |
| <p><b>Approval Criteria</b></p> <p><b>1 - Diagnosis of active psoriatic arthritis</b></p> <p><b>AND</b></p> <p><b>2 - One of the following:</b></p> <ul style="list-style-type: none"> <li>• Failure to a 3 month trial of methotrexate at the maximally indicated dose as confirmed by claims history or submission of medical records</li> <li>• History of intolerance or contraindication to methotrexate (please specify intolerance or contraindication)</li> <li>• Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of psoriatic arthritis as confirmed by claims history or submission of medical records [e.g., Cimzia (certolizumab), Cosentyx (secukinumab), adalimumab, Simponi (golimumab), Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), Otezla (apremilast), Skyrizi (risankizumab), Rinvoq (upadacitinib), Enbrel (etanercept), ustekinumab]</li> </ul> <p><b>AND</b></p> |                           |



**3** - One of the following:

**3.1** BOTH of the following:

**3.1.1** ONE of the following:

**3.1.1.1** Failure to two of the following as confirmed by claims history or submitted medical records

- One of the preferred adalimumab products\*
- Enbrel (etanercept)
- One of the preferred ustekinumab products\*

**OR**

**3.1.1.2** History of intolerance or contraindication to all of the following (please specify intolerance or contraindication)

- One of the preferred adalimumab products\*
- Enbrel (etanercept)
- One of the preferred ustekinumab products\*

**AND**

**3.1.2** ONE of the following:

- Failure to Cosentyx (secukinumab) as confirmed by claims history or submitted medical records
- History of intolerance or contraindication to Cosentyx (secukinumab) (please specify intolerance or contraindication)

**OR**

**3.2** Patient is currently on Bimzelx therapy as confirmed by claims history or submission of medical records

**AND**

**4** - Patient is not receiving Bimzelx in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept),

adalimumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast), ustekinumab]

**AND**

**5** - Prescribed by or in consultation with a rheumatologist or dermatologist

Notes

\*See PDL links in Background

Product Name: Bimzelx

Diagnosis Ankylosing Spondylitis (AS)

Approval Length 12 month(s)

Therapy Stage Initial Authorization

Guideline Type Prior Authorization

### Approval Criteria

**1** - Diagnosis of active ankylosing spondylitis

**AND**

**2** - One of the following:

- Failure to two NSAIDs (e.g., ibuprofen, naproxen) at maximally indicated doses, each used for at least 4 weeks, as confirmed by claims history or submission of medical records
- History of intolerance or contraindication to two NSAIDs (e.g., ibuprofen, naproxen) (please specify intolerance or contraindication)
- Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of ankylosing spondylitis as confirmed by claims history or submission of medical records [e.g., adalimumab, Simponi (golimumab), Rinvoq (upadacitinib), Xeljanz/Xeljanz XR (tofacitinib), Enbrel (etanercept)]

**AND**

**3** - One of the following:

**3.1** One of the following:

**3.1.1** Failure of ALL of the following as confirmed by claims history or submitted medical records

- One of the preferred adalimumab products\*
- Enbrel (etanercept)
- Cosentyx (secukinumab)

**OR**

**3.1.2** History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication):

- One of the preferred adalimumab products\*
- Enbrel (etanercept)
- Cosentyx (secukinumab)

**OR**

**3.2** Patient is currently on Bimzelx therapy as confirmed by claims history or submission of medical records

**AND**

**4** - Patient is not receiving Bimzelx in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Cosentyx (secukinumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

**AND**

**5** - Prescribed by or in consultation with a rheumatologist

Notes

\*See PDL links in Background

Product Name: Bimzelx

Diagnosis

Non-radiographic Axial Spondyloarthritis

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                       |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1 - Diagnosis of active non-radiographic axial spondyloarthritis</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>2 - One of the following:</b></p> <ul style="list-style-type: none"> <li>• Failure to two NSAIDs (e.g., ibuprofen, naproxen) at maximally indicated doses, each used for at least 4 weeks, as confirmed by claims history or submission of medical records</li> <li>• History of intolerance or contraindication to two NSAIDs (e.g., ibuprofen, naproxen) (please specify intolerance or contraindication)</li> <li>• Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of non-radiographic axial spondyloarthritis as confirmed by claims history or submission of medical records [e.g. Cimzia (certolizumab), Cosentyx (secukinumab), Rinvoq (upadacitinib)]</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>3 - One of the following:</b></p> <ul style="list-style-type: none"> <li>• Failure to Cosentyx (secukinumab) as confirmed by claims history or submitted medical records</li> <li>• History of intolerance or contraindication to Cosentyx (secukinumab) (please specify intolerance or contraindication)</li> <li>• Patient is currently on Bimzelx therapy as confirmed by claims history or submission of medical records</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>4 - Patient is not receiving Bimzelx in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Cosentyx (secukinumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]</b></p> |                       |

**AND**

**5** - Prescribed by or in consultation with a rheumatologist

|       |                              |
|-------|------------------------------|
| Notes | *See PDL links in Background |
|-------|------------------------------|

Product Name:Bimzelx

|           |                               |
|-----------|-------------------------------|
| Diagnosis | Hidradenitis Suppurativa (HS) |
|-----------|-------------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

### Approval Criteria

**1** - Diagnosis of moderate to severe hidradenitis suppurativa (i.e., Hurley Stage II or III)

**AND**

**2** - ONE of the following:

- Failure to at least one oral antibiotic (e.g., doxycycline, clindamycin, rifampin) at maximally indicated doses, as confirmed by claims history or submission of medical records
- History of contraindication or intolerance to at least one oral antibiotic (e.g., doxycycline, clindamycin, rifampin) (please specify contraindication or intolerance)
- Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of hidradenitis suppurativa as confirmed by claims history or submitted medical records [e.g., adalimumab, Cosentyx (secukinumab)]

**AND**

**3** - ONE of the following:

**3.1** ONE of the following:

**3.1.1** Failure to both of the following preferred products confirmed by claims history or submission of medical records

- One of the preferred adalimumab products\*
- Cosentyx (secukinumab)

**OR**

**3.1.2** History of contraindication or intolerance to both of the following preferred products (please specify contraindication or intolerance)

- One of the preferred adalimumab products\*
- Cosentyx (secukinumab)

**OR**

**3.2** Patient is currently on Bimzelx therapy as confirmed by claims history or submission of medical records

**AND**

**4** - Patient is not receiving Bimzelx in combination with another targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab), Xeljanz (tofacitinib)]

**AND**

**5** - Prescribed by or in consultation with a dermatologist

Notes

\*See PDL links in Background

Product Name: Bimzelx

Diagnosis

Plaque Psoriasis (PsO), Psoriatic Arthritis (PsA), Ankylosing Spondylitis (AS), Non-radiographic Axial Spondyloarthritis, Hidradenitis Suppurativa (HS)

Approval Length

12 month(s)

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                               |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------|
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Reauthorization                                                               |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Prior Authorization                                                           |
| <p><b>Approval Criteria</b></p> <p>1 - Documentation of positive clinical response to Bimzelx therapy</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Patient is not receiving Bimzelx in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Stelara (ustekinumab), Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]*</p> |                                                                               |
| Notes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | *Examples of drug(s) may not be applicable based on the requested indication. |

## 2 . Background

| Benefit/Coverage/Program Information                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p><b>PDL links:</b></p> <p>CO: <a href="https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html</a></p> <p>HI: <a href="https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html</a></p> <p>MD: <a href="https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-cp-pharmacy.html</a></p> <p>NJ: <a href="https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html</a></p> |

|                                                                                                                                                                                                                                                                                        |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| NM: <a href="https://www.uhcprovider.com/en/health-plans-by-state/new-mexico-health-plans/nm-comm-plan-home/nm-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/new-mexico-health-plans/nm-comm-plan-home/nm-cp-pharmacy.html</a>                                |
| NY: <a href="https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html</a>                                    |
| PA CHIP: <a href="https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP">https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP</a> |
| RI: <a href="https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html</a>                            |

### 3 . Revision History

| Date      | Notes                                                                                                                                                                                                                                                                                                          |
|-----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 2/17/2025 | Updated Cosentyx step in PsO section. Removed requirement that one of the steps in PsO must be adalimumab. Changed references of brand Stelara to generic ustekinumab. Removed Ilumya step in PsO section and added preferred ustekinumab as step therapy option. Added criteria for hidradenitis suppurativa. |



Bonjesta and Diclegis



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-228323                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Guideline Name</b> | Bonjesta and Diclegis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 6/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                                                                      |                     |
|----------------------------------------------------------------------|---------------------|
| Product Name:generic doxylamine/pyridoxine, Brand Diclegis, Bonjesta |                     |
| Approval Length                                                      | 9 month(s)          |
| Guideline Type                                                       | Prior Authorization |
| Approval Criteria                                                    |                     |

**1** - Diagnosis of nausea and vomiting associated with pregnancy

**AND**

**2** - Documented failure or contraindication to lifestyle modifications (e.g., diet, avoidance of triggers)

**AND**

**3** - ONE of the following:

**3.1** Failure to a five day trial of over-the-counter doxylamine taken together with pyridoxine (i.e., not a combined dosage form, but separate formulations taken concomitantly), as confirmed by claims history or submission of medical records

**OR**

**3.2** History of contraindication or intolerance to over-the-counter doxylamine taken together with pyridoxine (i.e., not a combined dosage form, but separate formulations taken concomitantly) (please specify contraindication or intolerance)

## 2 . Revision History

| Date     | Notes               |
|----------|---------------------|
| 4/3/2025 | Updated formularies |

Bonsity, Forteo



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-373463                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Guideline Name</b> | Bonsity, Forteo                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 10/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                                                                               |                       |
|-------------------------------------------------------------------------------|-----------------------|
| Product Name: Brand Forteo, generic teriparatide, brand Teriparatide, Bonsity |                       |
| Diagnosis                                                                     | Osteoporosis          |
| Approval Length                                                               | 24 month(s)           |
| Therapy Stage                                                                 | Initial Authorization |
| Guideline Type                                                                | Prior Authorization   |

## **Approval Criteria**

**1 - ONE of the following:**

**1.1 BOTH of the following:**

- Patient is female
- Diagnosis of postmenopausal osteoporosis

**OR**

**1.2 BOTH of the following:**

- Patient is male
- Diagnosis of osteoporosis

**AND**

**2 - ONE of the following:**

**2.1** Patient is at high risk of fracture [e.g., recent fracture (e.g., within the past 12 months), fractures while on approved osteoporosis therapy, multiple fractures, fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids), very low T-score (e.g., less than -3.0), high risk for falls or history of injurious falls, and very high fracture probability by FRAX (fracture risk assessment tool) (e.g., major osteoporosis fracture greater than 30%, hip fracture greater than 4.5%)]

**OR**

**2.2** Patient has a history of failure to at least one other available osteoporosis therapy (e.g., alendronate, denosumab, risedronate, zoledronate) as confirmed by claims history or submission of medical records

**OR**

**2.3** Patient has contraindication or intolerance to at least one other available osteoporosis therapy (e.g., alendronate, denosumab, risedronate, zoledronate) (please specify contraindication or intolerance)

**AND**

**3 - ONE of the following:**

**3.1** Treatment duration has not exceeded a total of 24 months of cumulative use of parathyroid hormone analogs (e.g., Bonsity, teriparatide injection, Forteo, Tymlos) during the patient's lifetime

**OR**

**3.2 BOTH of the following:**

**3.2.1** Patient is currently or has previously been treated with parathyroid hormone analogs (e.g., Bonsity, teriparatide injection, Forteo, Tymlos)

**AND**

**3.2.2** The prescriber attests that the patient remains at or has returned to having a high risk for fracture

**AND**

**4 - ONE of the following:**

- Failure to Tymlos as confirmed by claims history or submission of medical records
- History of intolerance or contraindication to Tymlos (please specify contraindication or intolerance)

|                                                                               |                                                                        |
|-------------------------------------------------------------------------------|------------------------------------------------------------------------|
| Product Name: Brand Forteo, generic teriparatide, brand Teriparatide, Bonsity |                                                                        |
| Diagnosis                                                                     | Osteoporosis Associated with Sustained Systemic Glucocorticoid Therapy |
| Approval Length                                                               | 24 month(s)                                                            |
| Therapy Stage                                                                 | Initial Authorization                                                  |
| Guideline Type                                                                | Prior Authorization                                                    |

**Approval Criteria**

**1** - Diagnosis of glucocorticoid-induced osteoporosis

**AND**

**2** - History of prednisone or its equivalent at a dose greater than or equal to 5 mg (milligrams)/day as confirmed by claims history or submission of medical records

**AND**

**3** - ONE of the following:

**3.1** Patient is at high risk of fracture [e.g., recent fracture (e.g., within the past 12 months), fractures while on approved osteoporosis therapy, multiple fractures, fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids), very low T-score (e.g., less than -3.0), high risk for falls or history of injurious falls, and very high fracture probability by FRAX (fracture risk assessment tool) (e.g., major osteoporosis fracture greater than 30%, hip fracture greater than 4.5%)]

**OR**

**3.2** Patient has a history of failure to at least one other available osteoporosis therapy (e.g., alendronate, denosumab, risedronate, zoledronate) as confirmed by claims history or submission of medical records

**OR**

**3.3** Patient has contraindication or intolerance to at least one other available osteoporosis therapy (e.g., alendronate, denosumab, risedronate, zoledronate) (please specify contraindication or intolerance)

**AND**

**4** - ONE of the following:

**4.1** Treatment duration has not exceeded a total of 24 months of cumulative use of parathyroid hormone analogs (e.g., Bonsity, teriparatide injection, Forteo, Tymlos)

**OR**

**4.2** BOTH of the following:

**4.2.1** Patient is currently or has previously been treated with parathyroid hormone analogs (e.g., Bonsity, teriparatide injection, Forteo, Tymlos)

**AND**

**4.2.2** The prescriber attests that the patient remains at or has returned to having a high risk for fracture

|                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                      |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|
| Product Name: Brand Forteo, generic teriparatide, brand Teriparatide, Bonsity                                                                                                                                                                                                                                                                                                                                                                             |                                                                                      |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Osteoporosis, Osteoporosis Associated with Sustained Systemic Glucocorticoid Therapy |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                           | 12 month(s)                                                                          |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                             | Reauthorization                                                                      |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                            | Prior Authorization                                                                  |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Treatment duration of parathyroid hormones (e.g., Bonsity, teriparatide injection, Forteo, Tymlos) has not exceeded a total of 24 months during the patient's lifetime</p> <p><b>OR</b></p> <p><b>2</b> - The patient remains at or has returned to having a high risk for fracture despite a total of 24 months of use of parathyroid hormones (e.g., Bonsity, teriparatide injection, Forteo, Tymlos)</p> |                                                                                      |

## 2 . Revision History

| Date      | Notes                                                            |
|-----------|------------------------------------------------------------------|
| 8/25/2025 | Updated formularies. Added Bonsity to title and GL. Updated GPIs |



Bosulif



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-228219                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Guideline Name</b> | Bosulif                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 5/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                       |                                      |
|-----------------------|--------------------------------------|
| Product Name: Bosulif |                                      |
| Diagnosis             | Chronic Myelogenous/Myeloid Leukemia |
| Approval Length       | 12 month(s)                          |
| Therapy Stage         | Initial Authorization                |

|                                                                                                                                                                                                                                                                                                                                                                                      |                     |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                       | Prior Authorization |
| <b>Approval Criteria</b><br><br><b>1</b> - Patient must have a diagnosis of chronic myeloid leukemia<br><br><p style="text-align: center;"><b>AND</b></p> <b>2</b> - One of the following:<br><br><b>2.1</b> Patient is not a candidate for imatinib as attested by physician<br><br><p style="text-align: center;"><b>OR</b></p> <b>2.2</b> Patient is currently on Bosulif therapy |                     |

|                                                                                                                                           |                                                               |
|-------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------|
| Product Name: Bosulif                                                                                                                     |                                                               |
| Diagnosis                                                                                                                                 | Philadelphia Chromosome-Positive Acute Lymphoblastic Leukemia |
| Approval Length                                                                                                                           | 12 month(s)                                                   |
| Therapy Stage                                                                                                                             | Initial Authorization                                         |
| Guideline Type                                                                                                                            | Prior Authorization                                           |
| <b>Approval Criteria</b><br><br><b>1</b> - Patient must have a diagnosis of Philadelphia chromosome-positive acute lymphoblastic leukemia |                                                               |

|                       |                            |
|-----------------------|----------------------------|
| Product Name: Bosulif |                            |
| Diagnosis             | Myeloid/Lymphoid Neoplasms |
| Approval Length       | 12 month(s)                |
| Therapy Stage         | Initial Authorization      |
| Guideline Type        | Prior Authorization        |

**Approval Criteria**

1 - Patient must have a diagnosis of myeloid/lymphoid neoplasms with eosinophilia

**AND**

2 - Presence of ABL1 (gene) rearrangement

| Product Name:Bosulif                                                                                                      |                                                                                                                                 |
|---------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------|
| Diagnosis                                                                                                                 | Chronic Myelogenous/Myeloid Leukemia, Philadelphia Chromosome-Positive Acute Lymphoblastic Leukemia, Myeloid/Lymphoid Neoplasms |
| Approval Length                                                                                                           | 12 month(s)                                                                                                                     |
| Therapy Stage                                                                                                             | Reauthorization                                                                                                                 |
| Guideline Type                                                                                                            | Prior Authorization                                                                                                             |
| <p><b>Approval Criteria</b></p> <p>1 - Patient does not show evidence of progressive disease while on Bosulif therapy</p> |                                                                                                                                 |

| Product Name:Bosulif                                                                                                                                                      |                          |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|
| Diagnosis                                                                                                                                                                 | NCCN Recommended Regimen |
| Approval Length                                                                                                                                                           | 12 month(s)              |
| Therapy Stage                                                                                                                                                             | Initial Authorization    |
| Guideline Type                                                                                                                                                            | Prior Authorization      |
| <p><b>Approval Criteria</b></p> <p>1 - Bosulif will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium</p> |                          |

|                                                                                                    |                          |
|----------------------------------------------------------------------------------------------------|--------------------------|
| Product Name: Bosulif                                                                              |                          |
| Diagnosis                                                                                          | NCCN Recommended Regimen |
| Approval Length                                                                                    | 12 month(s)              |
| Therapy Stage                                                                                      | Reauthorization          |
| Guideline Type                                                                                     | Prior Authorization      |
| <b>Approval Criteria</b><br><br>1 - Documentation of positive clinical response to Bosulif therapy |                          |

## 2 . Revision History

| Date      | Notes               |
|-----------|---------------------|
| 3/26/2025 | Updated formularies |

Braftovi



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-354249                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Guideline Name</b> | Braftovi                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 9/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                       |                       |
|-----------------------|-----------------------|
| Product Name:Braftovi |                       |
| Diagnosis             | Melanoma              |
| Approval Length       | 12 month(s)           |
| Therapy Stage         | Initial Authorization |

| Guideline Type | Prior Authorization                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                | <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of melanoma</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Presence of BRAF V600E mutation</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Disease is one of the following:</p> <ul style="list-style-type: none"> <li>• Unresectable</li> <li>• Metastatic</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>4</b> - Used in combination with Mektovi (binimetinib)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>5</b> - ONE of the following:</p> <p><b>5.1</b> Patient has a contraindication or history of intolerance to ONE of the following regimens (please specify contraindication or intolerance)</p> <ul style="list-style-type: none"> <li>• Tafinlar (dabrafenib) plus Mekinist (trametinib)</li> <li>• Zelboraf (vemurafenib) plus Cotellic (cobimetinib)</li> </ul> <p style="text-align: center;"><b>OR</b></p> <p><b>5.2</b> Provider attests that the patient is not an appropriate candidate for either of the following regimens</p> |

- Tafinlar (dabrafenib) plus Mekinist (trametinib)
- Zelboraf (vemurafenib) plus Cotellic (cobimetinib)

**OR**

**5.3** For continuation of prior Braftovi therapy

| Product Name: Braftovi                                                                                                                                                                                               |                     |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Diagnosis                                                                                                                                                                                                            | Melanoma            |
| Approval Length                                                                                                                                                                                                      | 12 month(s)         |
| Therapy Stage                                                                                                                                                                                                        | Reauthorization     |
| Guideline Type                                                                                                                                                                                                       | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Patient does not show evidence of progressive disease while on Braftovi therapy</p> <p><b>AND</b></p> <p><b>2</b> - Used in combination with Mektovi (binimetinib)</p> |                     |

| Product Name: Braftovi                                                                |                       |
|---------------------------------------------------------------------------------------|-----------------------|
| Diagnosis                                                                             | Colon/Rectal Cancer   |
| Approval Length                                                                       | 12 month(s)           |
| Therapy Stage                                                                         | Initial Authorization |
| Guideline Type                                                                        | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of colon or rectal cancer</p> |                       |

**AND**

**2** - Presence of BRAF V600E mutation

**AND**

**3** - Disease is ONE of the following:

- Advanced
- Metastatic

**AND**

**4** - ONE of the following:

**4.1** BOTH of the following:

- Patient has received prior therapy with an oxaliplatin-based regimen (e.g., FOLFOX, CAPEOX)
- Used in combination with Erbitux (cetuximab) or Vectibix (panitumumab)

**OR**

**4.2** BOTH of the following:

**4.2.1** Patient has NOT received prior therapy with an oxaliplatin-based regimen (e.g., FOLFOX, CAPEOX)

**AND**

**4.2.2** Used in combination with BOTH of the following:

- Erbitux (cetuximab) or Vectibix (panitumumab)
- FOLFOX (fluorouracil, leucovorin, and oxaliplatin)



|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                     |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name: Braftovi                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                     |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Colon/Rectal Cancer |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 12 month(s)         |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p>1 - Patient does not show evidence of progressive disease while on Braftovi therapy</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Used in combination with ONE of the following:</p> <ul style="list-style-type: none"> <li>• Erbitux (cetuximab)</li> <li>• Vectibix (panitumumab)</li> <li>• Erbitux (cetuximab) and FOLFOX (fluorouracil, leucovorin, and oxaliplatin)</li> <li>• Vectibix (panitumumab) and FOLFOX</li> </ul> |                     |

|                                                                                                                                                                                     |                            |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|
| Product Name: Braftovi                                                                                                                                                              |                            |
| Diagnosis                                                                                                                                                                           | Non-Small Cell Lung Cancer |
| Approval Length                                                                                                                                                                     | 12 month(s)                |
| Therapy Stage                                                                                                                                                                       | Initial Authorization      |
| Guideline Type                                                                                                                                                                      | Prior Authorization        |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of non-small cell lung cancer (NSCLC)</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Presence of BRAF V600E mutation</p> |                            |

**AND**

**3** - Disease is one of the following:

- Advanced
- Recurrent
- Metastatic

**AND**

**4** - Used in combination with Mektovi (binimetinib)

**AND**

**5** - ONE of the following:

**5.1** Patient has a contraindication or history of intolerance to the following regimen (please specify contraindication or intolerance):

- Tafinlar (dabrafenib) plus Mekinist (trametinib)

**OR**

**5.2** Provider attests that the patient is not an appropriate candidate for the following regimen:

- Tafinlar (dabrafenib) plus Mekinist (trametinib)

**OR**

**5.3** For continuation of prior Braftovi therapy

|                        |                            |
|------------------------|----------------------------|
| Product Name: Braftovi |                            |
| Diagnosis              | Non-Small Cell Lung Cancer |
| Approval Length        | 12 month(s)                |
| Therapy Stage          | Reauthorization            |

|                                                                                                                                                                                                                                           |                     |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Guideline Type                                                                                                                                                                                                                            | Prior Authorization |
| <b>Approval Criteria</b><br><br><b>1</b> - Patient does not show evidence of progressive disease while on Braftovi therapy<br><br><p style="text-align: center;"><b>AND</b></p> <b>2</b> - Used in combination with Mektovi (binimetinib) |                     |

|                                                                                                                                                |                          |
|------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|
| Product Name: Braftovi                                                                                                                         |                          |
| Diagnosis                                                                                                                                      | NCCN Recommended Regimen |
| Approval Length                                                                                                                                | 12 month(s)              |
| Therapy Stage                                                                                                                                  | Initial Authorization    |
| Guideline Type                                                                                                                                 | Prior Authorization      |
| <b>Approval Criteria</b><br><br><b>1</b> - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium |                          |

|                                                                                                            |                          |
|------------------------------------------------------------------------------------------------------------|--------------------------|
| Product Name: Braftovi                                                                                     |                          |
| Diagnosis                                                                                                  | NCCN Recommended Regimen |
| Approval Length                                                                                            | 12 month(s)              |
| Therapy Stage                                                                                              | Reauthorization          |
| Guideline Type                                                                                             | Prior Authorization      |
| <b>Approval Criteria</b><br><br><b>1</b> - Documentation of positive clinical response to Braftovi therapy |                          |

## 2 . Revision History

| Date     | Notes                                                          |
|----------|----------------------------------------------------------------|
| 8/5/2025 | Combined colon and rectal cancer sections and updated criteria |

Brexafemme



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-228220                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Guideline Name</b> | Brexafemme                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 5/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                          |                          |
|--------------------------|--------------------------|
| Product Name: Brexafemme |                          |
| Diagnosis                | Vulvovaginal candidiasis |
| Approval Length          | 3 month(s)               |
| Guideline Type           | Prior Authorization      |

### Approval Criteria

**1** - Diagnosis of vulvovaginal candidiasis (VVC)

**AND**

**2** - ONE of the following:

**2.1** Confirmed azole resistance demonstrated by culture and susceptibility testing

**OR**

**2.2** BOTH of the following:

**2.2.1** Other causes (including but not limited to bacterial vaginosis or trichomoniasis) have been ruled out

**AND**

**2.2.2** Failure of a 7-day course of oral fluconazole therapy defined as 100 mg (milligrams), 150 mg, or 200 mg taken orally every third day for a total of 3 doses (days 1,4, and 7), confirmed by claims history or submission of medical records, for the current episode of VVC

**AND**

**3** - Prescribed by or in consultation with ONE of the following:

- Infectious disease physician
- Obstetrician/Gynecologist

|                          |                                    |
|--------------------------|------------------------------------|
| Product Name: Brexafemme |                                    |
| Diagnosis                | Recurrent vulvovaginal candidiasis |
| Approval Length          | 6 month(s)                         |
| Guideline Type           | Prior Authorization                |

### Approval Criteria

1 - Diagnosis of recurrent vulvovaginal candidiasis (RVVC)

**AND**

2 - ONE of the following:

2.1 Confirmed azole resistance demonstrated by culture and susceptibility testing

**OR**

2.2 BOTH of the following:

2.2.1 Other causes (including but not limited to bacterial vaginosis or trichomoniasis) have been ruled out

**AND**

2.2.2 Failure of a maintenance course of oral fluconazole confirmed by claims history or submission of medical records defined as 100-mg, 150-mg, or 200-mg taken weekly for 6 months

**AND**

3 - Prescribed by or in consultation with ONE of the following:

- Infectious disease physician
- Obstetrician/Gynecologist

## 2 . Revision History

| Date | Notes |
|------|-------|
|------|-------|

|           |                     |
|-----------|---------------------|
| 3/27/2025 | Updated formularies |
|-----------|---------------------|



Brilinta



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-373464                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Guideline Name</b> | Brilinta                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 10/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                                                  |                     |
|--------------------------------------------------|---------------------|
| Product Name: Brand Brilinta, generic ticagrelor |                     |
| Approval Length                                  | 12 month(s)         |
| Guideline Type                                   | Prior Authorization |
| Approval Criteria                                |                     |

**1** - Diagnosis of acute coronary syndrome (ACS) [e.g., unstable angina (UA), non-ST elevation myocardial infarction (NSTEMI) or ST-segment elevation myocardial infarction (STEMI)]

**OR**

**2** - The medication is being used to reduce the risk of a first myocardial infarction (MI) or stroke in a patient with coronary artery disease (CAD) at high risk for such events [e.g., type 2 diabetes mellitus, hypertension, dyslipidemia, multi-vessel CAD, obesity, heart failure, current smoker or chronic kidney disease]

**OR**

**3** - The medication is being used to reduce the risk of stroke in patients with acute ischemic stroke (NIH Stroke Scale score less than or equal to 5) or high-risk transient ischemic attack (TIA)

## 2 . Revision History

| Date      | Notes                                         |
|-----------|-----------------------------------------------|
| 8/25/2025 | Removed Effient and generic from title and GL |

Bronchitol



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-234229                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Guideline Name</b> | Bronchitol                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Arizona (ACUAZ, ACUAZEC)</li> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania (ACUPA)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 6/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                         |             |
|-------------------------|-------------|
| Product Name:Bronchitol |             |
| Approval Length         | 12 month(s) |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                       |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                     | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                    | Prior Authorization   |
| <b>Approval Criteria</b><br><br><b>1</b> - Diagnosis of cystic fibrosis (CF)<br><br><p style="text-align: center;"><b>AND</b></p> <b>2</b> - Used in conjunction with standard CF therapies [e.g., chest physiotherapy, bronchodilators, antibiotics, anti-inflammatory therapy (e.g., ibuprofen, oral/inhaled corticosteroids)]<br><br><p style="text-align: center;"><b>AND</b></p> <b>3</b> - Patient has passed the Bronchitol Tolerance Test |                       |

|                                                                                                              |                     |
|--------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Bronchitol                                                                                      |                     |
| Approval Length                                                                                              | 12 month(s)         |
| Therapy Stage                                                                                                | Reauthorization     |
| Guideline Type                                                                                               | Prior Authorization |
| <b>Approval Criteria</b><br><br><b>1</b> - Documentation of positive clinical response to Bronchitol therapy |                     |

## 2 . Revision History

| Date      | Notes               |
|-----------|---------------------|
| 4/10/2025 | Updated formularies |

Brukinsa



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-398247                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Guideline Name</b> | Brukinsa                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 10/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                        |                       |
|------------------------|-----------------------|
| Product Name: Brukinsa |                       |
| Diagnosis              | B-Cell Lymphomas      |
| Approval Length        | 12 month(s)           |
| Therapy Stage          | Initial Authorization |

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Prior Authorization |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1 - ALL of the following:</b></p> <p><b>1.1</b> Diagnosis of follicular lymphoma (FL)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>1.2</b> Disease is relapsed or refractory</p> <p style="text-align: center;"><b>AND</b></p> <p><b>1.3</b> Patient has received at least two or more lines of systemic therapy</p> <p style="text-align: center;"><b>AND</b></p> <p><b>1.4</b> Brukinsa will be used in combination with obinutuzumab</p> <p style="text-align: center;"><b>OR</b></p> <p><b>2 - ALL of the following:</b></p> <p><b>2.1</b> Diagnosis of ONE of the following:</p> <ul style="list-style-type: none"> <li>• Extranodal marginal zone lymphoma (EMZL) of the stomach</li> <li>• Extranodal marginal zone lymphoma of nongastric sites (noncutaneous)</li> <li>• Nodal marginal zone lymphoma</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>2.2</b> Disease is relapsed, refractory, or progressive</p> |                     |

**AND**

**2.3** Patient has received at least one anti-CD20-based regimen (e.g., rituximab, obinutuzumab)

**OR**

**3** - ALL of the following:

**3.1** Diagnosis of splenic marginal zone lymphoma

**AND**

**3.2** Disease is relapsed or refractory

**AND**

**3.3** Patient has received at least one anti-CD20-based regimen (e.g., rituximab, obinutuzumab)

**OR**

**4** - Diagnosis of mantle cell lymphoma (MCL)

|                          |                                      |
|--------------------------|--------------------------------------|
| Product Name:Brukinsa    |                                      |
| Diagnosis                | Waldenström's Macroglobulinemia (WM) |
| Approval Length          | 12 month(s)                          |
| Therapy Stage            | Initial Authorization                |
| Guideline Type           | Prior Authorization                  |
| <b>Approval Criteria</b> |                                      |

**1 - Diagnosis of Waldenström's macroglobulinemia (WM)**

|                                                                                                                       |                                                                   |
|-----------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| Product Name:Brukinsa                                                                                                 |                                                                   |
| Diagnosis                                                                                                             | Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL) |
| Approval Length                                                                                                       | 12 month(s)                                                       |
| Therapy Stage                                                                                                         | Initial Authorization                                             |
| Guideline Type                                                                                                        | Prior Authorization                                               |
| <b>Approval Criteria</b><br><b>1 - Diagnosis of chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL)</b> |                                                                   |

|                                                                                                                                                                                         |                       |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Brukinsa                                                                                                                                                                   |                       |
| Diagnosis                                                                                                                                                                               | Hairy Cell Leukemia   |
| Approval Length                                                                                                                                                                         | 12 month(s)           |
| Therapy Stage                                                                                                                                                                           | Initial Authorization |
| Guideline Type                                                                                                                                                                          | Prior Authorization   |
| <b>Approval Criteria</b><br><b>1 - Diagnosis of hairy cell leukemia</b><br><br><p style="text-align: center;"><b>AND</b></p> <b>2 - Disease is relapsed, refractory, or progressive</b> |                       |

|                       |                                                                                                                                                |
|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------|
| Product Name:Brukinsa |                                                                                                                                                |
| Diagnosis             | B-Cell Lymphomas, Waldenström's Macroglobulinemia (WM), Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL), Hairy Cell Leukemia |



|                                                                                                                            |                     |
|----------------------------------------------------------------------------------------------------------------------------|---------------------|
| Approval Length                                                                                                            | 12 month(s)         |
| Therapy Stage                                                                                                              | Reauthorization     |
| Guideline Type                                                                                                             | Prior Authorization |
| <b>Approval Criteria</b><br><br><b>1</b> - Patient does not show evidence of progressive disease while on Brukinsa therapy |                     |

|                                                                                                                                                |                           |
|------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Brukinsa                                                                                                                          |                           |
| Diagnosis                                                                                                                                      | NCCN Recommended Regimens |
| Approval Length                                                                                                                                | 12 month(s)               |
| Therapy Stage                                                                                                                                  | Initial Authorization     |
| Guideline Type                                                                                                                                 | Prior Authorization       |
| <b>Approval Criteria</b><br><br><b>1</b> - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium |                           |

|                                                                                                            |                           |
|------------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Brukinsa                                                                                      |                           |
| Diagnosis                                                                                                  | NCCN Recommended Regimens |
| Approval Length                                                                                            | 12 month(s)               |
| Therapy Stage                                                                                              | Reauthorization           |
| Guideline Type                                                                                             | Prior Authorization       |
| <b>Approval Criteria</b><br><br><b>1</b> - Documentation of positive clinical response to Brukinsa therapy |                           |

## 2 . Revision History

| Date      | Notes                                                                                                                                                                                                                                                                           |
|-----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 9/17/2025 | Combined formularies. Added new GPI for Brukinsa tablet formulation. Updated B-cell lymphoma formatting (initial auth section) with no changes to clinical intent. Consolidated reauth section for hairy cell leukemia with the other indications that share the same criteria. |

Buphenyl



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-373488                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Guideline Name</b> | Buphenyl                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 10/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                                                                                     |                             |
|-------------------------------------------------------------------------------------|-----------------------------|
| Product Name: Brand Buphenyl oral powder, generic sodium phenylbutyrate oral powder |                             |
| Diagnosis                                                                           | Urea Cycle Disorders (UCDs) |
| Approval Length                                                                     | 12 month(s)                 |

|                                                                                 |                     |
|---------------------------------------------------------------------------------|---------------------|
| Guideline Type                                                                  | Prior Authorization |
| <b>Approval Criteria</b><br><b>1 - Diagnosis of urea cycle disorders (UCDs)</b> |                     |

|                                                                                                                                                                                                                                                                                               |                             |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|
| Product Name:Brand Buphenyl tablets, generic sodium phenylbutyrate tablets                                                                                                                                                                                                                    |                             |
| Diagnosis                                                                                                                                                                                                                                                                                     | Urea Cycle Disorders (UCDs) |
| Approval Length                                                                                                                                                                                                                                                                               | 12 month(s)                 |
| Therapy Stage                                                                                                                                                                                                                                                                                 | Initial Authorization       |
| Guideline Type                                                                                                                                                                                                                                                                                | Prior Authorization         |
| <b>Approval Criteria</b><br><b>1 - Diagnosis of urea cycle disorders (UCDs)</b><br><br><p style="text-align: center;"><b>AND</b></p> <b>2 - Prescriber provides a reason or special circumstance the patient cannot use sodium phenylbutyrate (generic Buphenyl) powder for oral solution</b> |                             |

|                                                                                                                                |                             |
|--------------------------------------------------------------------------------------------------------------------------------|-----------------------------|
| Product Name:Brand Buphenyl tablets, generic sodium phenylbutyrate tablets                                                     |                             |
| Diagnosis                                                                                                                      | Urea Cycle Disorders (UCDs) |
| Approval Length                                                                                                                | 12 month(s)                 |
| Therapy Stage                                                                                                                  | Reauthorization             |
| Guideline Type                                                                                                                 | Prior Authorization         |
| <b>Approval Criteria</b><br><b>1 - Documentation of positive clinical response to Buphenyl (sodium phenylbutyrate) tablets</b> |                             |

## 2 . Revision History

| Date      | Notes                                                  |
|-----------|--------------------------------------------------------|
| 8/26/2025 | Combined formularies. No changes to clinical criteria. |

Buprenorphine for Opioid Dependence



## Prior Authorization Guideline

|                       |                                                                                                         |
|-----------------------|---------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-161694                                                                                               |
| <b>Guideline Name</b> | Buprenorphine for Opioid Dependence                                                                     |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>Medicaid - Community &amp; State New Jersey (PSI2300)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 1/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                                                                                                                                                                                                                                                                                                                            |                     |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Brand Suboxone sublingual film, Zubsolv*                                                                                                                                                                                                                                                                      |                     |
| Diagnosis                                                                                                                                                                                                                                                                                                                  | Opioid Use Disorder |
| Approval Length                                                                                                                                                                                                                                                                                                            | 12 month(s)         |
| Guideline Type                                                                                                                                                                                                                                                                                                             | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p>1 - There must be a reason or special circumstance that the patient cannot use both of the following (please specify reason or special circumstance)**:</p> <ul style="list-style-type: none"> <li>Buprenorphine/naloxone sublingual film (generic Suboxone sublingual film)</li> </ul> |                     |

|                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                 |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"> <li>Buprenorphine/naloxone sublingual tablet</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - The requested quantity does not exceed 32 mg of buprenorphine daily</p> |                                                                                                                                                                                                                                                                 |
| Notes                                                                                                                                                                                                                          | <p>*Up to 32 mg per day of buprenorphine, or equivalent dosing of an alternative medication, will be authorized for the initial and/or reauthorization periods</p> <p>**NJ Psych Panel (any mental health prescriber) would override non-p referred status.</p> |

|                                                                                                                                                                                                                                                                                                                               |                                                         |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------|
| Product Name: Brand Suboxone sublingual film, generic buprenorphine/naloxone sublingual film, buprenorphine/naloxone sublingual tablet, Zubsolv, buprenorphine sublingual tablet *                                                                                                                                            |                                                         |
| Approval Length                                                                                                                                                                                                                                                                                                               | 12 month(s)                                             |
| Guideline Type                                                                                                                                                                                                                                                                                                                | Quantity Limit                                          |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - The physician has provided rationale for the need to exceed the buprenorphine daily limit</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - The requested dosage cannot be achieved using the plan accepted quantity limit of a different dose or formulation</p> |                                                         |
| Notes                                                                                                                                                                                                                                                                                                                         | *Authorization will be issued at the requested quantity |

## 2 . Revision History

| Date      | Notes                                           |
|-----------|-------------------------------------------------|
| 12/5/2024 | Minor language updates with no change to intent |

Bylvay



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-413208                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Guideline Name</b> | Bylvay                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Pennsylvania (ACUPA)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 11/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                     |                                               |
|---------------------|-----------------------------------------------|
| Product Name:Bylvay |                                               |
| Diagnosis           | Progressive Familial Intrahepatic Cholestasis |
| Approval Length     | 12 month(s)                                   |
| Therapy Stage       | Initial Authorization                         |
| Guideline Type      | Prior Authorization                           |



### Approval Criteria

**1** - Confirmed molecular diagnosis of progressive familial intrahepatic cholestasis (PFIC)

**AND**

**2** - Patient does not have a ABCB11 variant resulting in non-functional or complete absence of bile salt export pump protein (BSEP-3)

**AND**

**3** - Patient is experiencing moderate to severe pruritus associated with PFIC

**AND**

**4** - Patient has a serum bile acid concentration above the upper limit of the normal reference range for the reporting laboratory

**AND**

**5** - Patient has had an inadequate response to at least TWO other conventional treatments for the symptomatic relief of pruritus (e.g., ursodeoxycholic acid, diphenhydramine, cholestyramine, rifampin, naltrexone, sertraline)

**AND**

**6** - Prescribed by a gastroenterologist or hepatologist

|                     |                                               |
|---------------------|-----------------------------------------------|
| Product Name:Bylvay |                                               |
| Diagnosis           | Progressive Familial Intrahepatic Cholestasis |
| Approval Length     | 12 month(s)                                   |
| Therapy Stage       | Reauthorization                               |

|                                                                                                                                                                                                                                                                                                                    |                     |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Guideline Type                                                                                                                                                                                                                                                                                                     | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of positive clinical response to Bylvay therapy (e.g., reduced serum bile acids, improved pruritis, and less sleep disturbance)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Prescribed by a gastroenterologist or hepatologist</p> |                     |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                       |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Bylvay                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                       |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Alagille Syndrome     |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of Alagille syndrome (ALGS)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Confirmation of diagnosis by presence of the JAG1 or Notch2 gene mutation</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Patient has a serum bile acid concentration above the upper limit of the normal reference range for the reporting laboratory</p> <p style="text-align: center;"><b>AND</b></p> |                       |

**4** - Patient is experiencing moderate to severe pruritis associated with ALGS

**AND**

**5** - Patient has had an inadequate response to at least TWO other conventional treatments for the symptomatic relief of pruritus (e.g., ursodeoxycholic acid, diphenhydramine, cholestyramine, rifampin, naltrexone, sertraline).

**AND**

**6** - Prescribed by a gastroenterologist or hepatologist

|                                                                                                                                                                                                                                                            |                     |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Bylvay                                                                                                                                                                                                                                        |                     |
| Diagnosis                                                                                                                                                                                                                                                  | Alagille Syndrome   |
| Approval Length                                                                                                                                                                                                                                            | 12 month(s)         |
| Therapy Stage                                                                                                                                                                                                                                              | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                             | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of positive clinical response to Bylvay therapy (e.g., reduced serum bile acids, improved pruritis)</p> <p><b>AND</b></p> <p><b>2</b> - Prescribed by a gastroenterologist or hepatologist</p> |                     |

## 2 . Revision History

| Date | Notes |
|------|-------|
|------|-------|

|           |                                                                                                                                                         |
|-----------|---------------------------------------------------------------------------------------------------------------------------------------------------------|
| 10/8/2025 | Combined formularies. Minor update made to add "of" verbiage in dx check criterion for ALGS (initial auth section), with no changes to clinical intent. |
|-----------|---------------------------------------------------------------------------------------------------------------------------------------------------------|

C&S Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) Clinical Review



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-450232                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Guideline Name</b> | C&S Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) Clinical Review                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Florida MMA (CSFL, CSFLD)</li> <li>• Medicaid - Community &amp; State Louisiana (ACULA, ACULAC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State Michigan (ACUMI)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State Pennsylvania (ACUPA)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 12/1/2025 |
|-----------------|-----------|

## 1 . Criteria



|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                  |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Exception to Policy Limitations for Medicaid Patients Less Than 21 Years of Age^ |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 12 month(s)                                                                      |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Prior Authorization                                                              |
| <p><b>Approval Criteria</b></p> <p><b>1 - ONE of the following:</b></p> <p><b>1.1</b> The use of the requested medication is for an indicated diagnosis that is supported by the Food and Drug Administration (FDA)</p> <p style="text-align: center;"><b>OR</b></p> <p><b>1.2</b> The use of the requested medication is supported by information from ONE of the following appropriate compendia of current literature:</p> <ul style="list-style-type: none"> <li>• American Hospital Formulary Service Drug Information</li> <li>• National Comprehensive Cancer Network Drugs and Biologics Compendium</li> <li>• Thomson Micromedex DrugDex</li> <li>• Clinical pharmacology</li> <li>• United States Pharmacopoeia-National Formulary</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>2 - The use of the requested medication is NOT for experimental or investigational purposes</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>3 - Prescriber attests that the requested medication is medically necessary to correct or ameliorate a defect, physical or mental illness, or a condition (health problem)</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>4 - Prescriber attests the requested medication is an accepted method for treatment (medical practice)</b></p> |                                                                                  |

**AND**

**5** - Prescriber attests the requested medication is the least costly treatment of equally effective choices

**AND**

**6** - Prescriber attests the requested medication is safe and effective

**AND**

**7** - Submission of previous and current treatments used to treat diagnosis (Must include regimen, duration, treatment goals, and response to treatment)

**AND**

**8** - The requested medication is prescribed within the dosing guidelines from ONE of the following:

**8.1** The manufacturer's published dosing guidelines

**OR**

**8.2** ONE of the following compendia:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopoeia-National Formulary

Notes

^ This criteria does not apply to CSFLD and ACUFLEC. Note: ACUFL EC does not have Rx benefits.  
^ This criteria does NOT apply to ACUNE/ ACUNEEL1

## 2 . Revision History

| Date       | Notes                |
|------------|----------------------|
| 11/14/2025 | Added LA into scope. |



Cabliivi



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-263196                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Guideline Name</b> | Cabliivi                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Pennsylvania (ACUPA)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 7/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                        |                                                     |
|------------------------|-----------------------------------------------------|
| Product Name: Cabliivi |                                                     |
| Diagnosis              | Acquired thrombotic thrombocytopenic purpura (aTTP) |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                       |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 2 month(s)            |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of acquired thrombotic thrombocytopenic purpura (aTTP)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Cablivi was initiated as a bolus intravenous injection administered by a healthcare provider in combination with plasma exchange therapy</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Cablivi will be used in combination with immunosuppressive therapy (e.g., corticosteroids)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>4</b> - Total treatment duration will be limited to 58 days beyond the last therapeutic plasma exchange</p> |                       |

|                                                                                                                                                                                                                                                                                                            |                                                     |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------|
| Product Name:Cablivi                                                                                                                                                                                                                                                                                       |                                                     |
| Diagnosis                                                                                                                                                                                                                                                                                                  | Acquired thrombotic thrombocytopenic purpura (aTTP) |
| Approval Length                                                                                                                                                                                                                                                                                            | 2 month(s)                                          |
| Therapy Stage                                                                                                                                                                                                                                                                                              | Reauthorization                                     |
| Guideline Type                                                                                                                                                                                                                                                                                             | Prior Authorization                                 |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Request is for a new (different) episode requiring the re-initiation of plasma exchange for the treatment of acquired thrombotic thrombocytopenic purpura (aTTP) (Documentation of date of prior episode and documentation date of new episode required)</p> |                                                     |

## 2 . Revision History

| Date      | Notes               |
|-----------|---------------------|
| 5/14/2025 | Updated formularies |

Cabometyx



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-433290                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Guideline Name</b> | Cabometyx                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 12/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                         |                       |
|-------------------------|-----------------------|
| Product Name: Cabometyx |                       |
| Diagnosis               | Kidney cancer         |
| Approval Length         | 12 month(s)           |
| Therapy Stage           | Initial Authorization |

|                                                                                                                                                                                                                                                                     |                     |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Guideline Type                                                                                                                                                                                                                                                      | Prior Authorization |
| <b>Approval Criteria</b><br><br><b>1 - Diagnosis of ONE of the following:</b> <ul style="list-style-type: none"> <li>Advanced renal cell carcinoma (RCC)</li> <li>Relapsed renal cell carcinoma (RCC)</li> <li>Hereditary leiomyomatosis and RCC (HLRCC)</li> </ul> |                     |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                    |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|
| Product Name: Cabometyx                                                                                                                                                                                                                                                                                                                                                                                                                          |                                    |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                        | Non-Small Cell Lung Cancer (NSCLC) |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                  | 12 month(s)                        |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                    | Initial Authorization              |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                   | Prior Authorization                |
| <b>Approval Criteria</b><br><br><b>1 - Diagnosis of non-small cell lung cancer (NSCLC)</b><br><br><p style="text-align: center;"><b>AND</b></p> <b>2 - Positive for RET gene rearrangements</b><br><br><p style="text-align: center;"><b>AND</b></p> <b>3 - Disease is ONE of the following:</b> <ul style="list-style-type: none"> <li>Recurrent</li> <li>Advanced</li> <li>Metastatic</li> </ul> <p style="text-align: center;"><b>AND</b></p> |                                    |

**4** - Used as subsequent therapy following progression on ONE of the following:

- Gavreto (pralsetinib)
- Retevmo (selpercatinib)

**Product Name:**Cabometyx

|           |                          |
|-----------|--------------------------|
| Diagnosis | Hepatocellular Carcinoma |
|-----------|--------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

**1** - Diagnosis of hepatocellular carcinoma

**AND**

**2** - Used as subsequent-line systemic therapy

**Product Name:**Cabometyx

|           |             |
|-----------|-------------|
| Diagnosis | Bone cancer |
|-----------|-------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

**1** - Diagnosis of ONE of the following:

- Dedifferentiated chondrosarcoma
- Ewing Sarcoma
- High-grade undifferentiated pleomorphic sarcoma (UPS)

- Mesenchymal chondrosarcoma
- Osteosarcoma
- Primary round cell tumor of the bone (e.g., CIC::DUX4, BCOR::CCNB3)

**AND**

**2** - Disease is ONE of the following:

- Relapsed/refractory
- Metastatic

**AND**

**3** - Used as second line therapy

|                                                                                                                                                                                                                                                                                                                                                                                |                                        |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------|
| Product Name: Cabometyx                                                                                                                                                                                                                                                                                                                                                        |                                        |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                      | Gastrointestinal Stromal Tumors (GIST) |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                | 12 month(s)                            |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                  | Initial Authorization                  |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                 | Prior Authorization                    |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of gastrointestinal stromal tumors (GIST)</p> <p><b>AND</b></p> <p><b>2</b> - Patient has ONE of the following:</p> <ul style="list-style-type: none"> <li>• Gross residual disease (R2 resection)</li> <li>• Unresectable primary disease</li> <li>• Tumor rupture</li> <li>• Recurrent/metastatic disease</li> </ul> |                                        |

**AND**

**3** - Disease has progressed on ALL of the following:

- imatinib (generic Gleevec)
- sunitinib (generic Sutent)
- Stivarga (regorafenib)
- Standard dose Qinlock (ripretinib)

|                                                                                                                                                                                                  |                       |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name: Cabometyx                                                                                                                                                                          |                       |
| Diagnosis                                                                                                                                                                                        | Endometrial Carcinoma |
| Approval Length                                                                                                                                                                                  | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                    | Initial Authorization |
| Guideline Type                                                                                                                                                                                   | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of endometrial carcinoma</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Used as second-line or subsequent treatment</p> |                       |

|                                 |                       |
|---------------------------------|-----------------------|
| Product Name: Cabometyx         |                       |
| Diagnosis                       | Thyroid Cancer        |
| Approval Length                 | 12 month(s)           |
| Therapy Stage                   | Initial Authorization |
| Guideline Type                  | Prior Authorization   |
| <p><b>Approval Criteria</b></p> |                       |



**1** - Diagnosis of differentiated thyroid cancer (DTC)

**AND**

**2** - Disease is locally advanced or metastatic

**AND**

**3** - Disease has progressed following prior VEGFR-targeted therapy

**AND**

**4** - Disease is radioactive iodine-refractory or ineligible

**Product Name:**Cabometyx

|           |                     |
|-----------|---------------------|
| Diagnosis | Soft Tissue Sarcoma |
|-----------|---------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

### **Approval Criteria**

**1** - ALL of the following

**1.1** Diagnosis of ONE of the following soft tissue sarcoma subtypes:

- Extremity/body wall
- Head/neck
- Pleomorphic Rhabdomyosarcoma (RMS)
- Retroperitoneal/intraabdominal

**AND**

**1.2** Disease is advanced/metastatic

**AND**

**1.3** Used as subsequent line of therapy

**OR**

**2** - Diagnosis of ONE of the following soft tissue sarcoma subtypes:

- Alveolar soft part sarcoma (ASPS)
- Epithelioid hemangioendothelioma
- Extraskkeletal myxoid chondrosarcoma

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|
| Product Name: Cabometyx                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                   |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Neuroendocrine and Adrenal Tumors |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 12 month(s)                       |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Initial Authorization             |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Prior Authorization               |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of ONE of the following neuroendocrine tumors:</p> <ul style="list-style-type: none"> <li>• Well-differentiated pancreatic neuroendocrine tumor (pNET)</li> <li>• Well-differentiated extra-pancreatic neuroendocrine tumor (epNET)</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Disease is ONE of the following:</p> <ul style="list-style-type: none"> <li>• Locally advanced</li> <li>• Metastatic</li> <li>• Unresectable</li> </ul> |                                   |

| Product Name: Cabometyx                                                                                              |                                                                                                                                                                                                                                 |
|----------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Diagnosis                                                                                                            | Kidney Cancer, Non-Small Cell Lung Cancer (NSCLC), Hepatocellular Carcinoma, Bone Cancer, Gastrointestinal Stromal Tumors (GIST), Endometrial Carcinoma, Thyroid Cancer, Soft Tissue Sarcoma, Neuroendocrine and Adrenal Tumors |
| Approval Length                                                                                                      | 12 month(s)                                                                                                                                                                                                                     |
| Therapy Stage                                                                                                        | Reauthorization                                                                                                                                                                                                                 |
| Guideline Type                                                                                                       | Prior Authorization                                                                                                                                                                                                             |
| <b>Approval Criteria</b><br><br>1 - Patient does not show evidence of progressive disease while on Cabometyx therapy |                                                                                                                                                                                                                                 |

| Product Name: Cabometyx                                                                                                                 |                          |
|-----------------------------------------------------------------------------------------------------------------------------------------|--------------------------|
| Diagnosis                                                                                                                               | NCCN Recommended Regimen |
| Approval Length                                                                                                                         | 12 month(s)              |
| Therapy Stage                                                                                                                           | Initial Authorization    |
| Guideline Type                                                                                                                          | Prior Authorization      |
| <b>Approval Criteria</b><br><br>1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium |                          |

| Product Name: Cabometyx  |                          |
|--------------------------|--------------------------|
| Diagnosis                | NCCN Recommended Regimen |
| Approval Length          | 12 month(s)              |
| Therapy Stage            | Reauthorization          |
| Guideline Type           | Prior Authorization      |
| <b>Approval Criteria</b> |                          |

1 - Documentation of positive clinical response to Cabometyx therapy

## 2 . Revision History

| Date       | Notes                                                                                                                                                                                                                                                                                           |
|------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 10/27/2025 | Combined formularies. Added new criteria for neuroendocrine and adrenal tumors. Updated criteria for kidney cancer, non-small cell lung cancer, hepatocellular carcinoma, bone cancer, and soft tissue sarcoma. Updated and rearranged indications for reauth criteria. Minor cosmetic updates. |

Calquence



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-329214                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Guideline Name</b> | Calquence                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 8/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                         |                            |
|-------------------------|----------------------------|
| Product Name: Calquence |                            |
| Diagnosis               | Mantle Cell Lymphoma (MCL) |
| Approval Length         | 12 month(s)                |
| Therapy Stage           | Initial Authorization      |

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Prior Authorization |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of mantle cell lymphoma (MCL)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - ONE of the following:</p> <p><b>2.1</b> ALL of the following:</p> <ul style="list-style-type: none"> <li>• Patient has not received prior therapy (e.g., bortezomib, rituximab) for MCL</li> <li>• Patient is ineligible for autologous hematopoietic stem cell transplantation (HSCT)</li> <li>• Used in combination with bendamustine and rituximab</li> </ul> <p style="text-align: center;"><b>OR</b></p> <p><b>2.2</b> Patient has received at least one prior therapy for MCL (e.g., bortezomib, rituximab)</p> |                     |

|                                                                                                                        |                                                         |
|------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------|
| Product Name:Calquence                                                                                                 |                                                         |
| Diagnosis                                                                                                              | Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma |
| Approval Length                                                                                                        | 12 month(s)                                             |
| Therapy Stage                                                                                                          | Initial Authorization                                   |
| Guideline Type                                                                                                         | Prior Authorization                                     |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of chronic lymphocytic leukemia/small lymphocytic lymphoma</p> |                                                         |

|                        |                  |
|------------------------|------------------|
| Product Name:Calquence |                  |
| Diagnosis              | B-Cell Lymphomas |
| Approval Length        | 12 month(s)      |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                       |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of ONE of the following:</p> <ul style="list-style-type: none"> <li>• Nodal Marginal Zone Lymphoma</li> <li>• Extranodal Marginal Zone Lymphoma (EMZL) of the stomach</li> <li>• Splenic Marginal Zone Lymphoma</li> <li>• Extranodal Marginal Zone Lymphoma of Nongastric Sites (Non-cutaneous)</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p>2 - Disease is recurrent, relapsed, refractory, or progressive</p> |                       |

|                                                                                                                                                                                                                                                                                                                                              |                                                          |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------|
| Product Name: Calquence                                                                                                                                                                                                                                                                                                                      |                                                          |
| Diagnosis                                                                                                                                                                                                                                                                                                                                    | Waldenström Macroglobulinemia/Lymphoplasmacytic Lymphoma |
| Approval Length                                                                                                                                                                                                                                                                                                                              | 12 month(s)                                              |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                | Initial Authorization                                    |
| Guideline Type                                                                                                                                                                                                                                                                                                                               | Prior Authorization                                      |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of Waldenström Macroglobulinemia/Lymphoplasmacytic Lymphoma</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - ONE of the following:</p> <ul style="list-style-type: none"> <li>• Patient did not respond to primary therapy</li> <li>• Disease is relapsed or progressive</li> </ul> |                                                          |

| Product Name:Calquence                                                                                               |                                                                                                                                                                 |
|----------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Diagnosis                                                                                                            | Mantle Cell Lymphoma (MCL), Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma, B-Cell Lymphomas, Waldenström Macroglobulinemia/Lymphoplasmacytic Lymphoma |
| Approval Length                                                                                                      | 12 month(s)                                                                                                                                                     |
| Therapy Stage                                                                                                        | Reauthorization                                                                                                                                                 |
| Guideline Type                                                                                                       | Prior Authorization                                                                                                                                             |
| <b>Approval Criteria</b><br><br>1 - Patient does not show evidence of progressive disease while on Calquence therapy |                                                                                                                                                                 |

| Product Name:Calquence                                                                                                                  |                                                                   |
|-----------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| Diagnosis                                                                                                                               | National Comprehensive Cancer Network (NCCN) Recommended Regimens |
| Approval Length                                                                                                                         | 12 month(s)                                                       |
| Therapy Stage                                                                                                                           | Initial Authorization                                             |
| Guideline Type                                                                                                                          | Prior Authorization                                               |
| <b>Approval Criteria</b><br><br>1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium |                                                                   |

| Product Name:Calquence   |                                                                   |
|--------------------------|-------------------------------------------------------------------|
| Diagnosis                | National Comprehensive Cancer Network (NCCN) Recommended Regimens |
| Approval Length          | 12 month(s)                                                       |
| Therapy Stage            | Reauthorization                                                   |
| Guideline Type           | Prior Authorization                                               |
| <b>Approval Criteria</b> |                                                                   |



1 - Documentation of positive clinical response to Calquence therapy

## 2 . Revision History

| Date      | Notes                                                                                                                      |
|-----------|----------------------------------------------------------------------------------------------------------------------------|
| 7/14/2025 | Updated formularies to add ACUIN for eff 8/1/2025. Minor grammatical/cosmetic updates, with no changes to clinical intent. |

Camzyos



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-428196                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Guideline Name</b> | Camzyos                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Pennsylvania (ACUPA)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 12/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                       |                       |
|-----------------------|-----------------------|
| Product Name: Camzyos |                       |
| Approval Length       | 12 month(s)           |
| Therapy Stage         | Initial Authorization |

| Guideline Type | Prior Authorization                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                | <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of obstructive hypertrophic cardiomyopathy (HCM)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Heart failure is classified as ONE of the following:</p> <ul style="list-style-type: none"> <li>• New York Heart Association (NYHA) class II heart failure</li> <li>• NYHA class III heart failure</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Patient has a left ventricular ejection fraction of greater than or equal to 55%</p> <p style="text-align: center;"><b>AND</b></p> <p><b>4</b> - Patient has a Valsalva left ventricular outflow tract (LVOT) peak gradient greater than or equal to 50 mmHg at rest or with provocation</p> <p style="text-align: center;"><b>AND</b></p> <p><b>5</b> - ONE of the following:</p> <p><b>5.1</b> Failure to ONE of the following as confirmed by claims history or submission of medical records:</p> <ul style="list-style-type: none"> <li>• Non-vasodilating beta blocker (e.g., atenolol, bisoprolol, metoprolol, propranolol)</li> <li>• Nondihydropyridine calcium channel blocker (i.e., diltiazem, verapamil)</li> </ul> <p style="text-align: center;"><b>OR</b></p> <p><b>5.2</b> History of contraindication or intolerance to BOTH of the following (please specify contraindication or intolerance):</p> |

- Non-vasodilating beta blocker (e.g., atenolol, bisoprolol, metoprolol, propranolol)
- Nondihydropyridine calcium channel blocker (i.e., diltiazem, verapamil)

**AND**

**6** - Camzyos is prescribed by, or in consultation with, a cardiologist

|                                                                                                                                                                                                                                                                                                                                                                                                 |                     |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Camzyos                                                                                                                                                                                                                                                                                                                                                                            |                     |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                 | 12 month(s)         |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                   | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                  | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of positive clinical response to therapy (e.g., reduction in NYHA class, no worsening in NYHA class)</p> <p><b>AND</b></p> <p><b>2</b> - Patient has a left ventricular ejection fraction of greater than or equal to 50%</p> <p><b>AND</b></p> <p><b>3</b> - Camzyos is prescribed by, or in consultation with, a cardiologist</p> |                     |

## 2 . Revision History

| Date       | Notes                                              |
|------------|----------------------------------------------------|
| 10/24/2025 | Updated formularies to add PA-CAID for eff 12/1/25 |

Caprelsa



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-159286                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Guideline Name</b> | Caprelsa                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>•</li> <li>•</li> <li>•</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 1/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                       |                       |
|-----------------------|-----------------------|
| Product Name:Caprelsa |                       |
| Diagnosis             | Thyroid Carcinoma     |
| Approval Length       | 12 month(s)           |
| Therapy Stage         | Initial Authorization |
| Guideline Type        | Prior Authorization   |

## **Approval Criteria**

**1 - ALL of the following:**

**1.1** Diagnosis of medullary thyroid cancer (MTC)

**AND**

**1.2** ONE of the following:

- Unresectable locoregional disease that is symptomatic or progressing
- Asymptomatic recurrent or persistent distant metastatic disease if unresectable and progressing
- Recurrent or persistent distant metastases if symptomatic disease or progression

**OR**

**2 - ALL of the following:**

**2.1** ONE of the following diagnoses:

- Follicular carcinoma
- Oncocytic carcinoma
- Papillary carcinoma

**AND**

**2.2** ONE of the following:

- Unresectable recurrent disease
- Persistent locoregional disease
- Metastatic disease

**AND**

**2.3** ONE of the following:

- Patient has symptomatic disease

- Patient has progressive disease

**AND**

**2.4** Disease is refractory to radioactive iodine treatment

|                                                                                                                            |                     |
|----------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Caprelsa                                                                                                      |                     |
| Diagnosis                                                                                                                  | Thyroid Carcinoma   |
| Approval Length                                                                                                            | 12 month(s)         |
| Therapy Stage                                                                                                              | Reauthorization     |
| Guideline Type                                                                                                             | Prior Authorization |
| <b>Approval Criteria</b><br><br><b>1</b> - Patient does not show evidence of progressive disease while on Caprelsa therapy |                     |

|                                                                                                                                                |                           |
|------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Caprelsa                                                                                                                          |                           |
| Diagnosis                                                                                                                                      | NCCN Recommended Regimens |
| Approval Length                                                                                                                                | 12 month(s)               |
| Therapy Stage                                                                                                                                  | Initial Authorization     |
| Guideline Type                                                                                                                                 | Prior Authorization       |
| <b>Approval Criteria</b><br><br><b>1</b> - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium |                           |

|                       |                           |
|-----------------------|---------------------------|
| Product Name:Caprelsa |                           |
| Diagnosis             | NCCN Recommended Regimens |
| Approval Length       | 12 month(s)               |
| Therapy Stage         | Reauthorization           |

|                                                                                                        |                     |
|--------------------------------------------------------------------------------------------------------|---------------------|
| Guideline Type                                                                                         | Prior Authorization |
| <b>Approval Criteria</b><br><b>1</b> - Documentation of positive clinical response to Caprelsa therapy |                     |

## 2 . Revision History

| Date      | Notes                                            |
|-----------|--------------------------------------------------|
| 11/5/2024 | Updated criteria for medullary thyroid carcinoma |



Carbaglu



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-377343                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Guideline Name</b> | Carbaglu                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Pennsylvania (ACUPA)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 10/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                                                      |                       |
|------------------------------------------------------|-----------------------|
| Product Name: Brand Carbaglu, generic carglumic acid |                       |
| Approval Length                                      | 12 month(s)           |
| Therapy Stage                                        | Initial Authorization |

|                                                                                                                                                                                                                                                                                 |                     |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Guideline Type                                                                                                                                                                                                                                                                  | Prior Authorization |
| <b>Approval Criteria</b><br><br><b>1 - Diagnosis of hyperammonemia due to ONE of the following:</b> <ul style="list-style-type: none"> <li>• N-acetylglutamate synthase (NAGS) deficiency</li> <li>• Propionic acidemia (PA)</li> <li>• Methylmalonic acidemia (MMA)</li> </ul> |                     |

|                                                                                                                 |                     |
|-----------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Brand Carbaglu, generic carglumic acid                                                             |                     |
| Approval Length                                                                                                 | 12 month(s)         |
| Therapy Stage                                                                                                   | Reauthorization     |
| Guideline Type                                                                                                  | Prior Authorization |
| <b>Approval Criteria</b><br><br><b>1 - Documentation of positive clinical response to the requested therapy</b> |                     |

## 2 . Revision History

| Date      | Notes                                                                                                                                                                                                                                                                |
|-----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 8/27/2025 | Combined formularies. Of note, previous reauth verbiage for VA/NE/PACAID was "Documentation of positive clinical response to therapy" but now will align with CORE to "Documentation of positive clinical response to the requested therapy" (same clinical intent). |

Cayston



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-228223                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Guideline Name</b> | Cayston                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 5/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                      |                      |
|----------------------|----------------------|
| Product Name:Cayston |                      |
| Diagnosis            | Cystic Fibrosis (CF) |
| Approval Length      | 12 month(s)          |
| Guideline Type       | Prior Authorization  |

### Approval Criteria

1 - Diagnosis of cystic fibrosis (CF)

**AND**

2 - ONE of the following:

**2.1** Failure to tobramycin solution for inhalation (generic Bethkis) confirmed by claims history or submission of medical records

**OR**

**2.2** History of intolerance or contraindication to tobramycin solution for inhalation (generic Bethkis) (please specify intolerance or contraindication)

## 2 . Revision History

| Date      | Notes               |
|-----------|---------------------|
| 3/27/2025 | Updated formularies |

Cerdelga and Zavesca



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-363189                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Guideline Name</b> | Cerdelga and Zavesca                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 9/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                        |                       |
|------------------------|-----------------------|
| Product Name: Cerdelga |                       |
| Approval Length        | 12 month(s)           |
| Therapy Stage          | Initial Authorization |

|                                                                                                                                                                                                                                                                                                                                                                            |                     |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Guideline Type                                                                                                                                                                                                                                                                                                                                                             | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of Gaucher disease type 1</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Patient is ONE of the following as detected by an FDA-cleared test:</p> <ul style="list-style-type: none"> <li>• CYP2D6 extensive metabolizer</li> <li>• CYP2D6 intermediate metabolizer</li> <li>• CYP2D6 poor metabolizer</li> </ul> |                     |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                       |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name: Brand Zavesca, generic miglustat, Yargesa                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                       |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - ALL of the following:</p> <p>1.1 Diagnosis of mild to moderate type 1 Gaucher disease</p> <p style="text-align: center;"><b>AND</b></p> <p>1.2 Patient is unable to receive enzyme replacement therapy due to ONE of the following conditions:</p> <ul style="list-style-type: none"> <li>• Allergy or hypersensitivity to enzyme replacement therapy</li> <li>• Poor venous access</li> <li>• Unavailability of enzyme replacement therapy (e.g., Cerezyme, VPRIV)</li> </ul> |                       |

**OR**

**2** - ALL of the following:

- Diagnosis of Niemann-Pick disease type C (NPC)
- Diagnosis has been genetically confirmed by mutation analysis of NPC1 and NPC2 genes
- Provider attests patient presents with neurological manifestations of NPC

|                                                                                               |                     |
|-----------------------------------------------------------------------------------------------|---------------------|
| Product Name:Cerdelga, Brand Zavesca, generic miglustat, Yargesa                              |                     |
| Approval Length                                                                               | 12 month(s)         |
| Therapy Stage                                                                                 | Reauthorization     |
| Guideline Type                                                                                | Prior Authorization |
| <b>Approval Criteria</b><br><b>1</b> - Documentation of positive clinical response to therapy |                     |

## 2 . Revision History

| Date      | Notes                         |
|-----------|-------------------------------|
| 8/11/2025 | Updated formularies to add IN |

CGRP



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-180190                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Guideline Name</b> | CGRP                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 4/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                                    |                       |
|------------------------------------|-----------------------|
| Product Name:Ajovy, Emgality 120mg |                       |
| Diagnosis                          | Migraines             |
| Approval Length                    | 12 month(s)           |
| Therapy Stage                      | Initial Authorization |
| Guideline Type                     | Prior Authorization   |
|                                    |                       |



## **Approval Criteria**

**1** - Diagnosis of migraine consistent with The International Classification of Headache Disorders, 3rd edition

**AND**

**2** - ONE of the following:

**2.1** 4 to 7 migraine days per month and at least ONE of the following:

- Less than 15 headache days per month
- Provider attests this is the patient's predominant headache diagnosis (i.e., primary driver of headaches is not a different, non-migrainous condition)

**OR**

**2.2** Greater than or equal to 8 migraine days per month

**AND**

**3** - ONE of the following:

**3.1** Failure (after a trial of at least two months), to TWO of the following prophylactic therapies or classes as confirmed by claims history or submission of medical records:

- A beta-blocker (i.e., atenolol, metoprolol, nadolol, propranolol, or timolol)\*
- Candesartan (generic Atacand)\*
- Divalproex sodium [generic Depakote/Depakote ER (extended-release)]
- OnabotulinumtoxinA (generic Botox)\*\*
- A serotonin-norepinephrine reuptake inhibitor [i.e., duloxetine (Cymbalta), venlafaxine (Effexor/Effexor XR)]
- Topiramate (generic Topamax)
- A tricyclic antidepressant [i.e., amitriptyline (Elavil), nortriptyline (Pamelor)]

**OR**

**3.2** History of intolerance or contraindication to TWO of the following prophylactic therapies or classes (please specify intolerance or contraindication):

- A beta-blocker (i.e., atenolol, metoprolol, nadolol, propranolol, or timolol)\*

- Candesartan (generic Atacand)\*
- Divalproex sodium [generic Depakote/Depakote ER (extended-release)]
- OnabotulinumtoxinA (generic Botox)\*\*
- A serotonin-norepinephrine reuptake inhibitor [i.e., duloxetine (Cymbalta), venlafaxine (Effexor/Effexor XR)]
- Topiramate (generic Topamax)
- A tricyclic antidepressant [i.e., amitriptyline (Elavil), nortriptyline (Pamelor)]

**AND**

**4** - Medication will NOT be used in combination with another CGRP (calcitonin gene-related peptide) antagonist or inhibitor used for the preventive treatment of migraines [e.g., Aimovig, Nurtec ODT (orally disintegrating tablet), Qulipta, Vyepti (eptinezumab-jjmr)]

|       |                                                                                                                                                                                                                        |
|-------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Notes | <p>*Timolol and candesartan are non-preferred and should not be included in denial to provider.</p> <p>**OnabotulinumtoxinA (generic Botox) is a medical benefit and should not be included in denial to provider.</p> |
|-------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                                                                                                                                                                                                                                                                                                                                                                                                                                |                       |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Aimovig                                                                                                                                                                                                                                                                                                                                                                                                           |                       |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                      | Migraines             |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                  | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                 | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of migraine consistent with The International Classification of Headache Disorders, 3rd edition</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - ONE of the following:</p> <p><b>2.1</b> 4 to 7 migraine days per month and at least ONE of the following:</p> <ul style="list-style-type: none"> <li>• Less than 15 headache days per month</li> </ul> |                       |

- Provider attests this is the patient's predominant headache diagnosis (i.e., primary driver of headaches is not a different, non-migrainous condition)

**OR**

**2.2** Greater than or equal to 8 migraine days per month

**AND**

**3** - ONE of the following:

**3.1** Failure (after a trial of at least two months), to TWO of the following prophylactic therapies or classes as confirmed by claims history or submission of medical records:

- A beta-blocker (i.e., atenolol, metoprolol, nadolol, propranolol, or timolol)\*
- Candesartan (generic Atacand)\*
- Divalproex sodium [generic Depakote/Depakote ER (extended-release)]
- OnabotulinumtoxinA (generic Botox)\*\*
- A serotonin-norepinephrine reuptake inhibitor [i.e., duloxetine (Cymbalta), venlafaxine (Effexor/Effexor XR)]
- Topiramate (generic Topamax)
- A tricyclic antidepressant [i.e., amitriptyline (Elavil), nortriptyline (Pamelor)]

**OR**

**3.2** History of intolerance or contraindication to TWO of the following prophylactic therapies or classes (please specify intolerance or contraindication):

- A beta-blocker (i.e., atenolol, metoprolol, nadolol, propranolol, or timolol)\*
- Candesartan (generic Atacand)\*
- Divalproex sodium [generic Depakote/Depakote ER (extended-release)]
- OnabotulinumtoxinA (generic Botox)\*\*
- A serotonin-norepinephrine reuptake inhibitor [i.e., duloxetine (Cymbalta), venlafaxine (Effexor/Effexor XR)]
- Topiramate (generic Topamax)
- A tricyclic antidepressant [i.e., amitriptyline (Elavil), nortriptyline (Pamelor)]

**AND**

**4** - ONE of the following:

**4.1** Failure (after a trial of at least three months), to BOTH of the following as documented by claims history or submission of medical records:

- Ajovy
- Emgality [120 mg (milligram) strength]

**OR**

**4.2** History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- Ajovy
- Emgality (120 mg strength)

**AND**

**5** - Medication will not be used in combination with another CGRP (calcitonin gene-related peptide) antagonist or inhibitor used for the preventive treatment of migraines [e.g., Ajovy, Emgality, Nurtec ODT (orally disintegrating tablet), Qulipta, Vyepti]

Notes

\*Timolol and candesartan are non-preferred and should not be included in denial to provider.  
 \*\*OnabotulinumtoxinA (generic Botox) is a medical benefit and should not be included in denial to provider.

Product Name: Aimovig, Ajovy, Emgality 120mg

Diagnosis

Migraines

Approval Length

12 month(s)

Therapy Stage

Reauthorization

Guideline Type

Prior Authorization

### Approval Criteria

**1** - Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity

**AND**

**2** - Medication will NOT be used in combination with another CGRP (calcitonin gene-related peptide) antagonist or inhibitor used for the preventive treatment of migraines [e.g., Nurtec ODT (orally disintegrating tablet), Qulipta, Vyepti]

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Emgality 100mg                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                           |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Episodic Cluster Headache |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 12 month(s)               |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Initial Authorization     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Prior Authorization       |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of episodic cluster headache</p> <p><b>AND</b></p> <p><b>2</b> - Patient has experienced at least 2 cluster periods lasting from 7 days to 365 days, separated by pain-free periods lasting at least three months</p> <p><b>AND</b></p> <p><b>3</b> - Medication will NOT be used in combination with another CGRP (calcitonin gene-related peptide) antagonist or inhibitor used for the preventive treatment of migraines [e.g., Aimovig, Ajovy, Nurtec ODT (orally disintegrating tablet), Qulipta, Vyepti]</p> |                           |

|                             |                           |
|-----------------------------|---------------------------|
| Product Name:Emgality 100mg |                           |
| Diagnosis                   | Episodic Cluster Headache |
| Approval Length             | 12 month(s)               |
| Therapy Stage               | Reauthorization           |
| Guideline Type              | Prior Authorization       |

### Approval Criteria

**1** - Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity

**AND**

**2** - Medication will NOT be used in combination with another CGRP (calcitonin gene-related peptide) antagonist or inhibitor used for the preventive treatment of migraines [e.g., Aimovig, Ajovy, Nurtec ODT (orally disintegrating tablet), Qulipta, Vyepti]

## 2 . Revision History

| Date      | Notes                                                                                                                                              |
|-----------|----------------------------------------------------------------------------------------------------------------------------------------------------|
| 2/19/2025 | Updated formularies. Updated prophylactic therapy drug list and requirement contraindication/intolerance count from all to two. Updated Botox note |

Cholbam



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-351201                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Guideline Name</b> | Cholbam                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 9/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                      |                       |
|----------------------|-----------------------|
| Product Name:Cholbam |                       |
| Approval Length      | 3 month(s)            |
| Therapy Stage        | Initial Authorization |
| Guideline Type       | Prior Authorization   |

**Approval Criteria**

1 - BOTH of the following:

1.1 Diagnosis of a bile acid synthesis disorder

**AND**

1.2 Bile acid synthesis disorder is due to single enzyme defects (SEDs)

**OR**

2 - ALL of the following:

2.1 Diagnosis of a peroxisomal disorder including Zellweger spectrum disorders

**AND**

2.2 Patient exhibits manifestations of liver disease, steatorrhea, or complications from decreased fat soluble vitamin absorption

**AND**

2.3 Cholbam is being used as adjunctive treatment

|                          |                     |
|--------------------------|---------------------|
| Product Name:Cholbam     |                     |
| Approval Length          | 12 month(s)         |
| Therapy Stage            | Reauthorization     |
| Guideline Type           | Prior Authorization |
| <b>Approval Criteria</b> |                     |



**1** - Documentation of positive clinical response to Cholbam therapy as evidenced by BOTH of the following:

**1.1** Improvement in liver function (e.g., aspartate aminotransferase [AST], alanine aminotransferase [ALT])

**AND**

**1.2** Absence of complete biliary obstruction

## **2 . Revision History**

| Date      | Notes                                                  |
|-----------|--------------------------------------------------------|
| 7/30/2025 | Combined formularies. No changes to clinical criteria. |

Cialis and Chewtadzy for BPH



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-421302                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Guideline Name</b> | Cialis and Chewtadzy for BPH                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 11/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                                                                       |                     |
|-----------------------------------------------------------------------|---------------------|
| Product Name:Chewtadzy 5mg, Brand Cialis 5 mg, generic tadalafil 5 mg |                     |
| Approval Length                                                       | 12 month(s)         |
| Guideline Type                                                        | Prior Authorization |
|                                                                       |                     |

### **Approval Criteria**

**1** - Diagnosis of benign prostatic hyperplasia (BPH)

**AND**

**2** - ONE of the following:

**2.1** Failure to BOTH of the following as confirmed by claims history or submission of medical records:

- Alpha Blockers: (e.g., tamsulosin, alfuzosin ER, doxazosin, or terazosin)
- 5-alpha reductase inhibitors (e.g., finasteride)

**OR**

**2.2** History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- Alpha Blockers: (e.g., tamsulosin, alfuzosin ER, doxazosin, or terazosin)
- 5-alpha reductase inhibitors (e.g., finasteride)

**AND**

**3** - Dose does not exceed 5 mg (milligrams) once daily

**AND**

**4** - If the request is for Chewtadzy, ONE of the following:

- Failure to tadalafil 5 mg (generic Cialis 5 mg) confirmed by claims history or submission of medical records
- History of intolerance or contraindication to tadalafil 5 mg (generic Cialis 5 mg) (please specify intolerance or contraindication)

## **2 . Revision History**

UnitedHealthcare Community Plan of New Jersey – Clinical Pharmacy Guidelines

| Date       | Notes               |
|------------|---------------------|
| 10/15/2025 | Updated formularies |

Cibinqo



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-246187                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Guideline Name</b> | Cibinqo                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 7/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                      |                       |
|----------------------|-----------------------|
| Product Name:Cibinqo |                       |
| Approval Length      | 12 month(s)           |
| Therapy Stage        | Initial Authorization |
| Guideline Type       | Prior Authorization   |

## **Approval Criteria**

**1** - Diagnosis of moderate-to-severe chronic atopic dermatitis

**AND**

**2** - ONE of the following:

**2.1** BOTH of the following:

**2.1.1** ONE of the following:

**2.1.1.1** Failure to TWO of the following therapeutic classes of topical therapies as confirmed by claims history or submission of medical records:

- One medium, high, or very-high potency topical corticosteroid\* [e.g., mometasone furoate (generic Elocon), fluocinolone acetonide (generic Synalar), fluocinonide (generic Lidex)]
- One topical calcineurin inhibitor [e.g., pimecrolimus (generic Elidel), tacrolimus (generic Protopic)]
- Eucrisa (crisaborole)

**OR**

**2.1.1.2** History of intolerance or contraindication to ALL of the following therapeutic classes of topical therapies (please specify intolerance or contraindication):

- One medium, high, or very-high potency topical corticosteroid\* [e.g., mometasone furoate (generic Elocon), fluocinolone acetonide (generic Synalar), fluocinonide (generic Lidex)]
- One topical calcineurin inhibitor [e.g., pimecrolimus (generic Elidel), tacrolimus (generic Protopic)]
- Eucrisa (crisaborole)

**AND**

**2.1.2** ONE of the following:

**2.1.2.1** BOTH of the following:

- Submission of medical records (e.g., chart notes, laboratory values) documenting a 3 month trial of a systemic drug product for the treatment of atopic dermatitis [e.g., Adbry (tralokinumab-ldrm), Dupixent (dupilumab), Ebglyss (lebrikizumab-lbkz), Nemluvio (nemolizumab-ilto), cyclosporine, azathioprine, methotrexate, mycophenolate mofetil, etc.]
- Physician attests that the patient was not adequately controlled with the documented systemic drug product

**OR**

**2.1.2.2** Physician attests that systemic treatment with ALL of the following FDA-approved chronic atopic dermatitis therapies is inadvisable (document drug and contraindication rationale):

- Adbry (tralokinumab-ldrm)
- Dupixent (dupilumab)
- Ebglyss (lebrikizumab-lbkz)
- Nemluvio (nemolizumab-ilto)

**OR**

**2.1.2.3** Patient has a documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure [refer to the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition Text Revision (DSM-V-TR) 300.29 for specific phobia diagnostic criteria]

**OR**

**2.2** Patient is currently on Cibinqo therapy as confirmed by claims history or submission of medical records

**AND**

**3** - Patient is NOT receiving Cibinqo in combination with any of the following:

- Targeted immunomodulator [e.g., Adbry (tralokinumab-ldrm), Dupixent (dupilumab), Ebglyss (lebrikizumab-lbkz), Nemluvio (nemolizumab-ilto), Olumiant (baricitinib), Opzelura (topical ruxolitinib), Rinvoq (upadacitinib), Xeljanz/XR (tofacitinib)]
- Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

**AND**

**4** - Prescribed by or in consultation with ONE of the following:

- Dermatologist
- Allergist
- Immunologist

Notes

\*See list of "Relative Potencies of Topical Corticosteroids" in Table 1 of the Background.

Product Name:Cibinqo

Approval Length 12 month(s)

Therapy Stage Reauthorization

Guideline Type Prior Authorization

### Approval Criteria

**1** - Documentation of positive clinical response to Cibinqo therapy

**AND**

**2** - Patient is NOT receiving Cibinqo in combination with any of the following:

- Targeted immunomodulator [e.g., Adbry (tralokinumab-ldrm), Dupixent (dupilumab), Ebglyss (lebrikizumab-lbkz), Nemluvio (nemolizumab-ilto), Olumiant (baricitinib), Opzelura (topical ruxolitinib), Rinvoq (upadacitinib), Xeljanz/XR (tofacitinib)]
- Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

**AND**

**3** - Prescribed by or in consultation with ONE of the following:

- Dermatologist
- Allergist



- Immunologist

## 2 . Background

| Benefit/Coverage/Program Information                   |                                      |                                 |              |
|--------------------------------------------------------|--------------------------------------|---------------------------------|--------------|
| Table 1: Relative potencies of topical corticosteroids |                                      |                                 |              |
| Class                                                  | Drug                                 | Dosage Form                     | Strength (%) |
| Very high potency                                      | Augmented betamethasone dipropionate | Ointment, gel                   | 0.05         |
|                                                        | Clobetasol propionate                | Cream, foam, ointment           | 0.05         |
|                                                        | Diflorasone diacetate                | Ointment                        | 0.05         |
|                                                        | Halobetasol propionate               | Cream, ointment                 | 0.05         |
| High Potency                                           | Amcinonide                           | Cream, lotion, ointment         | 0.1          |
|                                                        | Augmented betamethasone dipropionate | Cream, lotion                   | 0.05         |
|                                                        | Betamethasone dipropionate           | Cream, foam, ointment, solution | 0.05         |
|                                                        | Desoximetasone                       | Cream, ointment                 | 0.25         |
|                                                        | Desoximetasone                       | Gel                             | 0.05         |
|                                                        | Diflorasone diacetate                | Cream                           | 0.05         |
|                                                        | Fluocinonide                         | Cream, gel, ointment, solution  | 0.05         |
|                                                        | Halcinonide                          | Cream, ointment                 | 0.1          |
|                                                        | Mometasone furoate                   | Ointment                        | 0.1          |
|                                                        | Triamcinolone acetonide              | Cream, ointment                 | 0.5          |
|                                                        | Betamethasone valerate               | Cream, foam, lotion, ointment   | 0.1          |

|                      |                            |                                   |              |
|----------------------|----------------------------|-----------------------------------|--------------|
| Medium potency       | Clocortolone pivalate      | Cream                             | 0.1          |
|                      | Desoximetasone             | Cream                             | 0.05         |
|                      | Fluocinolone acetonide     | Cream, ointment                   | 0.025        |
|                      | Flurandrenolide            | Cream, ointment, lotion           | 0.05         |
|                      | Fluticasone propionate     | Cream                             | 0.05         |
|                      | Fluticasone propionate     | Ointment                          | 0.005        |
|                      | Mometasone furoate         | Cream, lotion                     | 0.1          |
|                      | Triamcinolone acetonide    | Cream, ointment, lotion           | 0.1          |
| Lower-medium potency | Hydrocortisone butyrate    | Cream, ointment, solution         | 0.1          |
|                      | Hydrocortisone probutate   | Cream                             | 0.1          |
|                      | Hydrocortisone valerate    | Cream, ointment                   | 0.2          |
|                      | Prednicarbate              | Cream                             | 0.1          |
| Low potency          | Alclometasone dipropionate | Cream, ointment                   | 0.05         |
|                      | Desonide                   | Cream, gel, foam, ointment        | 0.05         |
|                      | Fluocinolone acetonide     | Cream, solution                   | 0.01         |
| Lowest potency       | Dexamethasone              | Cream                             | 0.1          |
|                      | Hydrocortisone             | Cream, lotion, ointment, solution | 0.25, 0.5, 1 |
|                      | Hydrocortisone acetate     | Cream, ointment                   | 0.5-1        |

### 3 . Revision History

| Date      | Notes                                                                                                                               |
|-----------|-------------------------------------------------------------------------------------------------------------------------------------|
| 4/24/2025 | Updated formularies. Added Ebglyss and Nemludio as an example of systemic drug product. Updated safety language for combination use |

Cimzia



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-180187                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Guideline Name</b> | Cimzia                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 4/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                     |                       |
|---------------------|-----------------------|
| Product Name:Cimzia |                       |
| Diagnosis           | Crohn's Disease       |
| Approval Length     | 12 month(s)           |
| Therapy Stage       | Initial Authorization |
| Guideline Type      | Prior Authorization   |

## **Approval Criteria**

**1** - ALL of the following:

**1.1** Diagnosis of moderately to severely active Crohn's disease

**AND**

**1.2** ONE of the following:

**1.2.1** Failure to ONE of the following confirmed by claims history or submitted medical records:

- Corticosteroids (e.g., prednisone, methylprednisolone, budesonide)
- Azathioprine (Imuran)
- 6-mercaptopurine (Purinethol)
- Methotrexate (Rheumatrex, Trexall)

**OR**

**1.2.2** History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication):

- Corticosteroids (e.g., prednisone, methylprednisolone, budesonide)
- Azathioprine (Imuran)
- 6-mercaptopurine (Purinethol)
- Methotrexate (Rheumatrex, Trexall)

**OR**

**1.2.3** Patient has been previously treated with a targeted immunomodulator FDA (Food and Drug Administration)-approved for the treatment of Crohn's disease as confirmed by claims history or submission of medical records [e.g., adalimumab, ustekinumab, Skyrizi (risankizumab)]

**AND**

**1.3** ONE of the following:

**1.3.1** Failure to ONE of the following as confirmed by claims history or submitted medical records:

- One of the preferred adalimumab products\*
- One of the preferred ustekinumab products\*

**OR**

**1.3.2** History of contraindication or intolerance to BOTH of the following (please specify contraindication or intolerance):

- One of the preferred adalimumab products\*
- One of the preferred ustekinumab products\*

**AND**

**1.4** Patient is NOT receiving Cimzia in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), ustekinumab, Skyrizi (risankizumab)]

**AND**

**1.5** Prescribed by or in consultation with a gastroenterologist

**OR**

**2** - ALL of the following:

**2.1** Patient is currently on Cimzia therapy as confirmed by claims history or submission of medical records

**AND**

**2.2** Diagnosis of moderately to severely active Crohn's disease

**AND**

**2.3** Patient is NOT receiving Cimzia in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), ustekinumab, Skyrizi (risankizumab)]

**AND**

**2.4** Prescribed by or in consultation with a gastroenterologist

Notes

\*See PDL links in Background

Product Name:Cimzia

Diagnosis Rheumatoid Arthritis (RA)

Approval Length 12 month(s)

Therapy Stage Initial Authorization

Guideline Type Prior Authorization

### Approval Criteria

**1** - ALL of the following:

**1.1** Diagnosis of moderately to severely active rheumatoid arthritis (RA)

**AND**

**1.2** ONE of the following:

**1.2.1** Failure to a 3 month trial of ONE non-biologic disease modifying anti-rheumatic drug (DMARD) [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine], at the maximally indicated doses, confirmed by claims history or submitted medical records

**OR**

**1.2.2** History of intolerance or contraindication to ONE non-biologic DMARD [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine] (please specify intolerance or contraindication)

**OR**

**1.2.3** Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of rheumatoid arthritis as confirmed by claims history or submission of medical records [e.g., Enbrel (etanercept), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

**AND**

**1.3** ONE of the following:

**1.3.1** Failure to ALL of the following as confirmed by claims history or submitted medical records:

- Enbrel (etanercept)
- One of the preferred adalimumab products\*
- Tyenne (tocilizumab-aazg)

**OR**

**1.3.2** History of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):

- Enbrel (etanercept)
- One of the preferred adalimumab products\*
- Tyenne (tocilizumab-aazg)

**AND**

**1.4** Patient is NOT receiving Cimzia in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

**AND**

**1.5** Prescribed by or in consultation with a rheumatologist

**OR**

**2 - ALL of the following:**

**2.1** Patient is currently on Cimzia therapy as confirmed by claims history or submission of medical records

**AND**

**2.2** Diagnosis of moderately to severely active rheumatoid arthritis (RA)

**AND**

**2.3** Patient is NOT receiving Cimzia in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

**AND**

**2.4** Prescribed by or in consultation with a rheumatologist

|       |                              |
|-------|------------------------------|
| Notes | *See PDL links in Background |
|-------|------------------------------|

|                                                                                                                                   |                       |
|-----------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Cimzia                                                                                                               |                       |
| Diagnosis                                                                                                                         | Psoriatic Arthritis   |
| Approval Length                                                                                                                   | 12 month(s)           |
| Therapy Stage                                                                                                                     | Initial Authorization |
| Guideline Type                                                                                                                    | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1 - ALL of the following:</b></p> <p><b>1.1</b> Diagnosis of active psoriatic arthritis</p> |                       |



**AND**

**1.2** ONE of the following:

**1.2.1** Failure to a 3 month trial of methotrexate, at the maximally indicated dose, confirmed by claims history or submitted medical records

**OR**

**1.2.2** History of intolerance or contraindication to methotrexate (please specify intolerance or contraindication)

**OR**

**1.2.3** Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of psoriatic arthritis as confirmed by claims history or submission of medical records [e.g., Enbrel (etanercept), adalimumab, Simponi (golimumab), Orencia (abatacept), ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

**AND**

**1.3** ONE of the following:

**1.3.1** Failure to TWO of the following as confirmed by claims history or submitted medical records:

- Enbrel (etanercept)
- One of the preferred adalimumab products\*
- One of the preferred ustekinumab products\*

**OR**

**1.3.2** History of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):

- Enbrel (etanercept)

- One of the preferred adalimumab products\*
- One of the preferred ustekinumab products\*

**AND**

**1.4** Patient is NOT receiving Cimzia in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), adalimumab, Simponi (golimumab), Orencia (abatacept), ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

**AND**

**1.5** Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Dermatologist

**OR**

**2** - ALL of the following:

**2.1** Patient is currently on Cimzia therapy as confirmed by claims history or submission of medical records

**AND**

**2.2** Diagnosis of active psoriatic arthritis

**AND**

**2.3** Patient is NOT receiving Cimzia in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), adalimumab, Simponi (golimumab), Orencia (abatacept), ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

**AND**

**2.4** Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Dermatologist

Notes

\*See PDL links in Background

**Product Name:**Cimzia

**Diagnosis** Ankylosing Spondylitis

**Approval Length** 12 month(s)

**Therapy Stage** Initial Authorization

**Guideline Type** Prior Authorization

### Approval Criteria

**1** - ALL of the following:

**1.1** Diagnosis of active ankylosing spondylitis

**AND**

**1.2** ONE of the following:

**1.2.1** Failure of TWO NSAIDs (non-steroidal anti-inflammatory drugs) (e.g., ibuprofen, naproxen) at maximally indicated doses, each used for at least 4 weeks, confirmed by claims history or submitted medical records

**OR**

**1.2.2** History of intolerance or contraindication to TWO NSAIDs (please specify intolerance or contraindication)

**OR**

**1.2.3** Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of ankylosing spondylitis as confirmed by claims history or submission of medical records [e.g., adalimumab, Simponi (golimumab), Xeljanz/Xeljanz XR (tofacitinib)]

**AND**

**1.3** ONE of the following:

**1.3.1** Failure to BOTH of the following as confirmed by claims history or submitted medical records:

- Enbrel (etanercept)
- One of the preferred adalimumab products\*

**OR**

**1.3.2** History of contraindication or intolerance to BOTH of the following (please specify contraindication or intolerance):

- Enbrel (etanercept)
- One of the preferred adalimumab products\*

**AND**

**1.4** Patient is NOT receiving Cimzia in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Simponi (golimumab), Oencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

**AND**

**1.5** Prescribed by or in consultation with a rheumatologist

**OR**

**2 - ALL of the following:**

**2.1** Patient is currently on Cimzia therapy as confirmed by claims history or submission of medical records

**AND**

**2.2** Diagnosis of active ankylosing spondylitis

**AND**

**2.3** Patient is NOT receiving Cimzia in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

**AND**

**2.4** Prescribed by or in consultation with a rheumatologist

|       |                              |
|-------|------------------------------|
| Notes | *See PDL links in Background |
|-------|------------------------------|

|                                                                                                                                                              |                       |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Cimzia                                                                                                                                          |                       |
| Diagnosis                                                                                                                                                    | Plaque Psoriasis      |
| Approval Length                                                                                                                                              | 12 month(s)           |
| Therapy Stage                                                                                                                                                | Initial Authorization |
| Guideline Type                                                                                                                                               | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1 - ALL of the following:</b></p> <p><b>1.1</b> Diagnosis of moderate to severe plaque psoriasis</p> <p><b>AND</b></p> |                       |

**1.2** ONE of the following:

**1.2.1** ALL of the following:

**1.2.1.1** Greater than or equal to 3% body surface area involvement, palmoplantar, facial, or genital involvement, or severe scalp psoriasis

**AND**

**1.2.1.2** ONE of the following:

**1.2.1.2.1** Failure to ONE of the following topical therapies, confirmed by claims history or submitted medical records:

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin
- Coal tar

**OR**

**1.2.1.2.2** History of intolerance or contraindication to ALL of the following topical therapies (please specify intolerance or contraindication):

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin
- Coal tar

**AND**

**1.2.1.3** ONE of the following:

**1.2.1.3.1** Failure to a 3 month trial of methotrexate at the maximally indicated dose, confirmed by claims history or submitted medical records

**OR**

**1.2.1.3.2** History of intolerance or contraindication to methotrexate (please specify intolerance or contraindication)

**OR**

**1.2.2** Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of plaque psoriasis as confirmed by claims history or submission of medical records [e.g., adalimumab, Otezla (apremilast), Skyrizi (risankizumab-rzaa), ustekinumab, Tremfya (guselkumab)]

**AND**

**1.3** ONE of the following:

**1.3.1** Failure to TWO of the following preferred products, confirmed by claims history or submitted medical records:

- One of the preferred adalimumab products\*
- Enbrel (etanercept)
- One of the preferred ustekinumab products\*

**OR**

**1.3.2** History of intolerance or contraindication to ALL of the following preferred products (please specify intolerance or contraindication)

- One of the preferred adalimumab products\*
- Enbrel (etanercept)
- One of the preferred ustekinumab products\*

**AND**

**1.4** Patient is NOT receiving Cimzia in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz

(ixekizumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

**AND**

**1.5** Prescribed by or in consultation with a dermatologist

**OR**

**2** - ALL of the following:

**2.1** Patient is currently on Cimzia therapy as confirmed by claims history or submission of medical records

**AND**

**2.2** Diagnosis of moderate to severe plaque psoriasis

**AND**

**2.3** Patient is NOT receiving Cimzia in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

**AND**

**2.4** Prescribed by or in consultation with a dermatologist

|       |                              |
|-------|------------------------------|
| Notes | *See PDL links in Background |
|-------|------------------------------|

|                     |                                          |
|---------------------|------------------------------------------|
| Product Name:Cimzia |                                          |
| Diagnosis           | Non-Radiographic Axial Spondyloarthritis |
| Approval Length     | 12 month(s)                              |
| Therapy Stage       | Initial Authorization                    |



| Guideline Type | Prior Authorization                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                | <p><b>Approval Criteria</b></p> <p><b>1 - ALL of the following:</b></p> <p><b>1.1</b> Diagnosis of non-radiographic axial spondyloarthritis</p> <p style="text-align: center;"><b>AND</b></p> <p><b>1.2 ONE of the following:</b></p> <p><b>1.2.1</b> Failure of TWO NSAIDs (non-steroidal anti-inflammatory drugs) (e.g., ibuprofen, naproxen) at maximally indicated doses, each used for at least 4 weeks, confirmed by claims history or submitted medical records</p> <p style="text-align: center;"><b>OR</b></p> <p><b>1.2.2</b> History of intolerance or contraindication to TWO NSAIDs (please specify intolerance or contraindication)</p> <p style="text-align: center;"><b>OR</b></p> <p><b>1.2.3</b> Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of non-radiographic axial spondyloarthritis as confirmed by claims history or submission of medical records [e.g., Cosentyx (secukinumab), Rinvoq (upadacitinib), Taltz (ixekizumab)]</p> <p style="text-align: center;"><b>AND</b></p> <p><b>1.3 ONE of the following:</b></p> <ul style="list-style-type: none"> <li>• Failure to Cosentyx (secukinumab) as confirmed by claims history or submitted medical records</li> <li>• History of contraindication or intolerance to Cosentyx (please specify contraindication or intolerance)</li> </ul> |

**AND**

**1.4** Patient is NOT receiving Cimzia in combination with another targeted immunomodulator [e.g., Cosentyx (secukinumab), Rinvoq (upadacitinib), Taltz (ixekizumab)]

**AND**

**1.5** Prescribed by or in consultation with a rheumatologist

**OR**

**2** - ALL of the following:

**2.1** Patient is currently on Cimzia therapy as confirmed by claims history or submission of medical records

**AND**

**2.2** Diagnosis of non-radiographic axial spondyloarthritis

**AND**

**2.3** Patient is NOT receiving Cimzia in combination with another targeted immunomodulator [e.g., Cosentyx (secukinumab), Rinvoq (upadacitinib), Taltz (ixekizumab)]

**AND**

**2.4** Prescribed by or in consultation with a rheumatologist

|                     |                                                    |
|---------------------|----------------------------------------------------|
| Product Name:Cimzia |                                                    |
| Diagnosis           | Polyarticular Juvenile Idiopathic Arthritis (pJIA) |
| Approval Length     | 12 month(s)                                        |
| Therapy Stage       | Initial Authorization                              |

| Guideline Type | Prior Authorization                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                | <p><b>Approval Criteria</b></p> <p><b>1 - ALL of the following:</b></p> <p><b>1.1</b> Diagnosis of active polyarticular juvenile idiopathic arthritis (pJIA)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>1.2</b> ONE of the following:</p> <p><b>1.2.1</b> Failure to ALL of the following as confirmed by claims history or submitted medical records:</p> <ul style="list-style-type: none"> <li>• Enbrel (etanercept)</li> <li>• One of the preferred adalimumab products*</li> <li>• Tyenne (tocilizumab-aazg)</li> </ul> <p style="text-align: center;"><b>OR</b></p> <p><b>1.2.2</b> History of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):</p> <ul style="list-style-type: none"> <li>• Enbrel (etanercept)</li> <li>• One of the preferred adalimumab products*</li> <li>• Tyenne (tocilizumab-aazg)</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>1.3</b> Patient is NOT receiving Cimzia in combination with another targeted immunomodulator [e.g., adalimumab, Enbrel (etanercept), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]</p> <p style="text-align: center;"><b>AND</b></p> <p><b>1.4</b> Prescribed by or in consultation with a rheumatologist</p> |

**OR**

**2 - ALL of the following:**

**2.1** Patient is currently on Cimzia therapy as confirmed by claims history or submission of medical records

**AND**

**2.2** Diagnosis of active polyarticular juvenile idiopathic arthritis (pJIA)

**AND**

**2.3** Patient is NOT receiving Cimzia in combination with another targeted immunomodulator [e.g., adalimumab, Enbrel (etanercept), Simponi (golimumab), Orenzia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

**AND**

**2.4** Prescribed by or in consultation with a rheumatologist

|       |                              |
|-------|------------------------------|
| Notes | *See PDL links in Background |
|-------|------------------------------|

|                                                                                                          |                                                                                                                                                                                                         |
|----------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Product Name:Cimzia                                                                                      |                                                                                                                                                                                                         |
| Diagnosis                                                                                                | Crohn's Disease, Rheumatoid Arthritis (RA), Psoriatic Arthritis, Ankylosing Spondylitis, Plaque Psoriasis, Non-Radiographic Axial Spondyloarthritis, Polyarticular Juvenile Idiopathic Arthritis (pJIA) |
| Approval Length                                                                                          | 12 month(s)                                                                                                                                                                                             |
| Therapy Stage                                                                                            | Reauthorization                                                                                                                                                                                         |
| Guideline Type                                                                                           | Prior Authorization                                                                                                                                                                                     |
| <b>Approval Criteria</b><br><br><b>1 - Documentation of positive clinical response to Cimzia therapy</b> |                                                                                                                                                                                                         |

**AND**

**2** - Patient is NOT receiving Cimzia in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), adalimumab, Simponi (golimumab), Orencia (abatacept), ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Siliq (brodalumab), Ilumya (tildrakizumab), Otezla (apremilast)]\*

Notes

\* Examples of drug(s) may not be applicable based on the requested indication.

## 2 . Background

### Benefit/Coverage/Program Information

#### PDL Links

CO: <https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html>

HI: <https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html>

MD: <https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-cp-pharmacy.html>

NJ: <https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html>

NM: <https://www.uhcprovider.com/en/health-plans-by-state/new-mexico-health-plans/nm-comm-plan-home/nm-cp-pharmacy.html>

NY: <https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html>

PA: <https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP>

RI: <https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html>

### 3 . Revision History

| Date      | Notes                                                                                                                                                                                |
|-----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 2/19/2025 | Updated formularies. Replaced Ilumya with ustekinumab as a step therapy option in PsO and added ustekinumab as ST option in CD and PsA. Replaced Stelara with ustekinumab throughout |

Cinryze



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-241187                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Guideline Name</b> | Cinryze                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 6/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                      |                             |
|----------------------|-----------------------------|
| Product Name:Cinryze |                             |
| Diagnosis            | Hereditary angioedema (HAE) |
| Approval Length      | 12 month(s)                 |
| Therapy Stage        | Initial Authorization       |
| Guideline Type       | Prior Authorization         |

### **Approval Criteria**

**1** - Diagnosis of hereditary angioedema (HAE) as confirmed by one of the following:

**1.1** C1 inhibitor (C1-INH) deficiency or dysfunction (Type I or II HAE) as documented by ONE of the following (per laboratory standard):

- C1-INH antigenic level below the lower limit of normal
- C1-INH functional level below the lower limit of normal

**OR**

**1.2** HAE with normal C1 inhibitor levels and ONE of the following:

- Confirmed presence of variant(s) in the gene(s) for factor XII, angiotensin-1, plasminogen-1, kininogen-1, myoferlin, and heparan sulfate-glucosamine 3-O-sulfotransferase 6
- Recurring angioedema attacks that are refractory to high-dose antihistamines with confirmed family history of angioedema
- Recurring angioedema attacks that are refractory to high-dose antihistamines with unknown background de-novo mutation(s) (i.e., no family history) (HAE-unknown)

**AND**

**2** - Prescribed for the prophylaxis of HAE attacks

**AND**

**3** - Not used in combination with other products indicated for prophylaxis against HAE attacks (e.g., Haegarda, Orladeyo, Takhzyro)

**AND**

**4** - Prescriber attests that the patient has experienced attacks of a severity and/or frequency such that they would clinically benefit from prophylactic therapy with Cinryze



**AND**

**5** - One of the following:

**5.1** Failure to Haegarda confirmed by claims history or submitted medical records

**OR**

**5.2** History of intolerance or contraindication to Haegarda (please specify intolerance or contraindication)

**OR**

**5.3** Patient is currently on Cinryze therapy confirmed by claims history or submitted medical records

**AND**

**6** - Prescribed by ONE of the following:

- Immunologist
- Allergist

|                                                                                                                  |                             |
|------------------------------------------------------------------------------------------------------------------|-----------------------------|
| Product Name:Cinryze                                                                                             |                             |
| Diagnosis                                                                                                        | Hereditary angioedema (HAE) |
| Approval Length                                                                                                  | 12 month(s)                 |
| Therapy Stage                                                                                                    | Reauthorization             |
| Guideline Type                                                                                                   | Prior Authorization         |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of positive clinical response to Cinryze therapy</p> |                             |

**AND**

**2** - Reduction in the utilization of on-demand therapies used for acute attacks (e.g., Berinert, Firazyr, Ruconest) as determined by claims information, while on Cinryze therapy

**AND**

**3** - Prescribed for the prophylaxis of HAE attacks

**AND**

**4** - Not used in combination with other products indicated for prophylaxis against HAE attacks (e.g., Haegarda, Orladeyo, Takhzyro)

**AND**

**5** - Prescribed by ONE of the following:

- Immunologist
- Allergist

## 2 . Revision History

| Date      | Notes               |
|-----------|---------------------|
| 4/10/2025 | Updated formularies |

Ciprodex



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-238235                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Guideline Name</b> | Ciprodex                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 6/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                                                                  |                     |
|------------------------------------------------------------------|---------------------|
| Product Name:Brand Ciprodex, generic ciprofloxacin/dexamethasone |                     |
| Approval Length                                                  | 1 Month             |
| Guideline Type                                                   | Prior Authorization |
| Approval Criteria                                                |                     |

1 - The patient has a perforated tympanic membrane or tympanostomy tubes

OR

2 - ONE of the following:

- Failure with ONE preferred alternative\* as confirmed by claims history or submission of medical records
- History of intolerance or contraindication to ONE preferred alternative\* (please specify intolerance or contraindication)

Notes

\*See PDL links in Background

## 2 . Background

### Benefit/Coverage/Program Information

#### PDL Links

CO: <https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html>

HI: <https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html>

MD: <https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-cp-pharmacy.html>

NJ: <https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html>

NM: <https://www.uhcprovider.com/en/health-plans-by-state/new-mexico-health-plans/nm-comm-plan-home/nm-cp-pharmacy.html>

NY: <https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html>

PA: <https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP>

RI: <https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html>

### 3 . Revision History

| Date      | Notes                                                    |
|-----------|----------------------------------------------------------|
| 4/16/2025 | Updated formularies. Formatting changes. Added PDL links |

Colony Stimulating Factors



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-180198                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Guideline Name</b> | Colony Stimulating Factors                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 4/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                              |                                  |
|------------------------------|----------------------------------|
| Product Name:Leukine, Zarxio |                                  |
| Diagnosis                    | Bone Marrow/Stem Cell Transplant |
| Approval Length              | 3 months or duration of therapy  |
| Guideline Type               | Prior Authorization              |

**Approval Criteria**

**1** - ONE of the following:

**1.1** Patient has non-myeloid malignancies and is undergoing myeloablative chemotherapy followed by autologous or allogeneic bone marrow transplant (BMT)

**OR**

**1.2** Used for mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis

**OR**

**1.3** Patient has had a peripheral stem cell transplant (PSCT) and has received myeloablative chemotherapy

**AND**

**2** - Prescribed by or in consultation with a hematologist or oncologist

|                                                                                                                                                                                                                                               |                                  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|
| Product Name: Neupogen, Nivestym, Nypozi, Releuko                                                                                                                                                                                             |                                  |
| Diagnosis                                                                                                                                                                                                                                     | Bone Marrow/Stem Cell Transplant |
| Approval Length                                                                                                                                                                                                                               | 3 months or duration of therapy  |
| Guideline Type                                                                                                                                                                                                                                | Prior Authorization              |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - ONE of the following:</p> <p><b>1.1</b> Patient has non-myeloid malignancies and is undergoing myeloablative chemotherapy followed by autologous or allogeneic bone marrow transplant (BMT)</p> |                                  |

**OR**

**1.2** Used for mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis

**OR**

**1.3** Patient has had a peripheral stem cell transplant (PSCT) and has received myeloablative chemotherapy

**AND**

**2** - Prescribed by or in consultation with a hematologist or oncologist

**AND**

**3** - ONE of the following:

**3.1** The request is for Neupogen vial, Nivestym vial, or Releuko vial AND the requested dose is less than 0.3 milliliters

**OR**

**3.2** Both of the following:

**3.2.1** Physician attestation that in their clinical opinion the clinical response would be expected to be superior with Neupogen, Nivestym, Nypozi, or Releuko than experienced with Zarxio

**AND**

**3.2.2** One of the following:

- Failure to Zarxio as confirmed by claims history or submission of medical records



- History of contraindication, intolerance or adverse event to Zarxio (please specify contraindication, intolerance, or adverse event)

|                              |                                        |
|------------------------------|----------------------------------------|
| Product Name:Leukine, Zarxio |                                        |
| Diagnosis                    | AML Induction or Consolidation Therapy |
| Approval Length              | 3 months or duration of therapy        |
| Guideline Type               | Prior Authorization                    |

**Approval Criteria**

1 - Diagnosis of acute myeloid leukemia (AML)

**AND**

2 - ONE of the following:

2.1 Patient achieved complete remission after induction therapy

**OR**

2.2 Patient is receiving consolidation chemotherapy

**OR**

2.3 Patient is receiving fludarabine, cytarabine with or without idarubicin for relapsed or refractory disease

**OR**

2.4 Patient is receiving cladribine, cytarabine with or without mitoxantrone or idarubicin for relapsed or refractory disease

**AND**

**3** - Prescribed by or in consultation with a hematologist or oncologist

Product Name: Neupogen, Nivestym, Nypozi, Releuko

|           |                                        |
|-----------|----------------------------------------|
| Diagnosis | AML Induction or Consolidation Therapy |
|-----------|----------------------------------------|

|                 |                                 |
|-----------------|---------------------------------|
| Approval Length | 3 months or duration of therapy |
|-----------------|---------------------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

### Approval Criteria

**1** - Diagnosis of acute myeloid leukemia (AML)

**AND**

**2** - One of the following:

**2.1** Patient achieved complete remission after induction therapy

**OR**

**2.2** Patient is receiving consolidation chemotherapy

**OR**

**2.3** Patient is receiving fludarabine, cytarabine with or without idarubicin for relapsed or refractory disease

**OR**

**2.4** Patient is receiving cladribine, cytarabine with or without mitoxantrone or idarubicin for relapsed or refractory disease

**AND**

**3** - Prescribed by or in consultation with a hematologist or oncologist

**AND**

**4** - ONE of the following:

**4.1** The request is for Neupogen vial, Nivestym vial, or Releuko vial AND the requested dose is less than 0.3 milliliters

**OR**

**4.2** Both of the following:

**4.2.1** Physician attestation that in their clinical opinion the clinical response would be expected to be superior with Neupogen, Nivestym, Nypozi, or Releuko than experienced with Zarxio

**AND**

**4.2.2** One of the following:

- Failure to Zarxio as confirmed by claims history or submission of medical records
- History of contraindication, intolerance or adverse effect to Zarxio (please specify contraindication, intolerance, or adverse effect)

|                                                                                 |                                                                      |
|---------------------------------------------------------------------------------|----------------------------------------------------------------------|
| Product Name:Leukine, Neulasta, Neulasta Onpro, Zarxio, Udenyca, Udenyca Onbody |                                                                      |
| Diagnosis                                                                       | Primary Prophylaxis of Chemotherapy-Induced Febrile Neutropenia (FN) |
| Approval Length                                                                 | 3 months or duration of therapy.                                     |
| Guideline Type                                                                  | Prior Authorization                                                  |
|                                                                                 |                                                                      |

## Approval Criteria

**1** - ONE of the following:

**1.1** One of the following:

- Patient is receiving dose dense MVAC (methotrexate, vinblastine, doxorubicin, cisplatin) for bladder cancer
- Patient is receiving dose dense AC (doxorubicin, cyclophosphamide) followed by dose-dense paclitaxel for breast cancer
- Patient is receiving chemotherapy regimen(s) associated with greater than 20% incidence of febrile neutropenia (FN)

**OR**

**1.2** Both of the following:

**1.2.1** Patient is receiving chemotherapy regimen(s) associated with 10-20% incidence of FN

**AND**

**1.2.2** Patient has one or more risk factors for chemotherapy-induced febrile neutropenia such as:

- Persistent neutropenia due to prior chemotherapy, radiation therapy, or bone marrow involvement by tumor (< 500 neutrophils/mcL or < 1,000 neutrophils/mcL and a predicted decline to ≤ 500 neutrophils/mcL over the next 48 hours)
- Liver dysfunction (bilirubin > 2.0)
- Renal dysfunction (creatinine clearance < 50)
- Age greater than 65 years receiving full chemotherapy dose intensity

**AND**

**2** - Prescribed by or in consultation with a hematologist or oncologist

|                                                           |                                                                      |
|-----------------------------------------------------------|----------------------------------------------------------------------|
| Product Name: Granix, Neupogen, Nivestym, Nypozi, Releuko |                                                                      |
| Diagnosis                                                 | Primary Prophylaxis of Chemotherapy-Induced Febrile Neutropenia (FN) |
| Approval Length                                           | 3 months or duration of therapy.                                     |
| Guideline Type                                            | Prior Authorization                                                  |

## **Approval Criteria**

**1 - ONE of the following:**

**1.1 One of the following:**

- Patient is receiving dose dense MVAC (methotrexate, vinblastine, doxorubicin, cisplatin) for bladder cancer
- Patient is receiving dose dense AC (doxorubicin, cyclophosphamide) followed by dose-dense paclitaxel for breast cancer
- Patient is receiving chemotherapy regimen(s) associated with greater than 20% incidence of febrile neutropenia (FN)

**OR**

**1.2 Both of the following:**

**1.2.1 Patient is receiving chemotherapy regimen(s) associated with 10-20% incidence of FN**

**AND**

**1.2.2 Patient has one or more risk factors for chemotherapy-induced febrile neutropenia such as:**

- Persistent neutropenia due to prior chemotherapy, radiation therapy, or bone marrow involvement by tumor ( $< 500$  neutrophils/mcL or  $< 1,000$  neutrophils/mcL and a predicted decline to  $\leq 500$  neutrophils/mcL over the next 48 hours)
- Liver dysfunction (bilirubin  $> 2.0$ )
- Renal dysfunction (creatinine clearance  $< 50$ )
- Age greater than 65 years receiving full chemotherapy dose intensity

**AND**

**2 - Prescribed by or in consultation with a hematologist or oncologist**

**AND**

**3 - ONE of the following:**

**3.1** The request is for Granix vial, Neupogen vial, Nivestym vial, or Releuko vial AND the requested dose is less than 0.3 milliliters

**OR**

**3.2** Both of the following:

**3.2.1** Physician attestation that in their clinical opinion the clinical response would be expected to be superior with Granix, Neupogen, Nivestym, Nypozi, or Releuko than experienced with Zarxio

**AND**

**3.2.2** One of the following:

- Failure to Zarxio as confirmed by claims history or submission of medical records
- History of contraindication, intolerance, or adverse effect to Zarxio (please specify contraindication, intolerance, or adverse effect)

|                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                      |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------|
| Product Name:Fulphila, Fylnetra, Nyvepria, Rolvedon, Stimufend, Ziextenzo                                                                                                                                                                                                                                                                                                                                         |                                                                      |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                         | Primary Prophylaxis of Chemotherapy-Induced Febrile Neutropenia (FN) |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                   | 3 months or duration of therapy                                      |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                    | Prior Authorization                                                  |
| <p><b>Approval Criteria</b></p> <p><b>1 - ONE</b> of the following:</p> <p><b>1.1</b> One of the following:</p> <ul style="list-style-type: none"> <li>• Patient is receiving dose dense MVAC (methotrexate, vinblastine, doxorubicin, cisplatin) for bladder cancer</li> <li>• Patient is receiving dose dense AC (doxorubicin, cyclophosphamide) followed by dose-dense paclitaxel for breast cancer</li> </ul> |                                                                      |

- Patient is receiving chemotherapy regimen(s) associated with greater than 20% incidence of febrile neutropenia (FN)

**OR**

**1.2** Both of the following:

**1.2.1** Patient is receiving chemotherapy regimen(s) associated with 10-20% incidence of FN

**AND**

**1.2.2** Patient has one or more risk factors for chemotherapy-induced febrile neutropenia:

- Persistent neutropenia due to prior chemotherapy, radiation therapy or bone marrow involvement by tumor (< 500 neutrophils/mcL or < 1,000 neutrophils/mcL and a predicted decline to ≤ 500 neutrophils/mcL over the next 48 hours)
- Liver dysfunction (bilirubin > 2.0)
- Renal dysfunction (creatinine clearance < 50)
- Age greater than 65 years receiving full chemotherapy dose intensity

**AND**

**2** - Prescribed by or in consultation with a hematologist or oncologist

**AND**

**3** - BOTH of the following:

**3.1** Physician attestation that in their clinical opinion the clinical response would be expected to be superior with Fulphila, Fylnetra, Nyvepria, Rolvedon, Stimufend or Ziextenzo than experienced with Neulasta or Udenyca/Udenyca Onbody

**AND**

**3.2** One of the following:

- Failure to Neulasta or Udenyca/Udenyca Onbody as confirmed by claims history or submission of medical records

- History of intolerance, contraindication, or adverse effect to Neulasta or Udenyca/Udenyca Onbody (please specify intolerance, contraindication or adverse effect)

|                                                                                 |                                                   |
|---------------------------------------------------------------------------------|---------------------------------------------------|
| Product Name:Leukine, Neulasta, Neulasta Onpro, Zarxio, Udenyca, Udenyca Onbody |                                                   |
| Diagnosis                                                                       | Secondary Prophylaxis of Febrile Neutropenia (FN) |
| Approval Length                                                                 | 3 months or duration of therapy                   |
| Guideline Type                                                                  | Prior Authorization                               |

**Approval Criteria**

1 - ONE of the following:

1.1 BOTH of the following:

1.1.1 ONE of the following:

1.1.1.1 Patient is receiving myelosuppressive anticancer drug(s) given with a curative intent (curative chemotherapy, chemotherapy in curative adjuvant/neoadjuvant setting)

**OR**

1.1.1.2 Patient is receiving myelosuppressive anticancer drug(s) with a non-curative intent and use of secondary prophylaxis is in accordance with the United States Food and Drug Administration approved labeling

**OR**

1.1.1.3 Patient is receiving myelosuppressive anticancer drug(s) for definitive therapy (bridge to stem cell transplant, organ transplant, definitive surgery for oligometastatic disease)

**AND**

1.1.2 ONE of the following:

1.1.2.1 Patient has a documented history of a neutropenic event (febrile neutropenia or low



neutrophil count leading to delay of subsequent cycle) during a previous cycle of the same chemotherapy regimen at full dose for which primary prophylaxis was not received

**OR**

**1.1.2.2** Patient has a documented history of neutropenic event from a previous course of chemotherapy

**OR**

**1.2** ONE of the following:

**1.2.1** BOTH of the following:

**1.2.1.1** Patient is receiving myelosuppressive anticancer drug(s) given with non-curative intent

**AND**

**1.2.1.2** Patient has a documented history of neutropenic event (febrile neutropenia or low neutrophil count leading to delay of subsequent cycle) during a previous cycle of the same chemotherapy regimen after a trial of dose reduction

**OR**

**1.2.2** Patient is receiving myelosuppressive anticancer drug(s) where primary prophylaxis is indicated

**AND**

**2** - Prescribed by or in consultation with a hematologist or oncologist

|                                                           |                                                   |
|-----------------------------------------------------------|---------------------------------------------------|
| Product Name: Granix, Neupogen, Nivestym, Nypozi, Releuko |                                                   |
| Diagnosis                                                 | Secondary Prophylaxis of Febrile Neutropenia (FN) |
| Approval Length                                           | 3 months or duration of therapy                   |
| Guideline Type                                            | Prior Authorization                               |

## **Approval Criteria**

**1 - ONE of the following:**

**1.1 BOTH of the following:**

**1.1.1 ONE of the following:**

**1.1.1.1** Patient is receiving myelosuppressive anticancer drug(s) given with a curative intent (curative chemotherapy, chemotherapy in curative adjuvant/neoadjuvant setting)

**OR**

**1.1.1.2** Patient is receiving myelosuppressive anticancer drug(s) with a non-curative intent and use of secondary prophylaxis is in accordance with the United States Food and Drug Administration approved labeling

**OR**

**1.1.1.3** Patient is receiving myelosuppressive anticancer drug(s) for definitive therapy (bridge to stem cell transplant, organ transplant, definitive surgery for oligometastatic disease)

**AND**

**1.1.2 ONE of the following:**

**1.1.2.1** Patient has a documented history of a neutropenic event (febrile neutropenia or low neutrophil count leading to delay of subsequent cycle) during a previous cycle of the same chemotherapy regimen at full dose for which primary prophylaxis was not received

**OR**

**1.1.2.2** Patient has a documented history of neutropenic event from a previous course of chemotherapy

**OR**

**1.2** ONE of the following:

**1.2.1** BOTH of the following:

**1.2.1.1** Patient is receiving myelosuppressive anticancer drug(s) given with non-curative intent

**AND**

**1.2.1.2** Patient has a documented history of neutropenic event (febrile neutropenia or low neutrophil count leading to delay of subsequent cycle) during a previous cycle of the same chemotherapy regimen after a trial of dose reduction

**OR**

**1.2.2** Patient is receiving myelosuppressive anticancer drug(s) where primary prophylaxis is indicated

**AND**

**2** - Prescribed by or in consultation with a hematologist or oncologist

**AND**

**3** - ONE of the following:

**3.1** The request is for Granix vial, Neupogen vial, Nivestym vial, or Releuko vial AND the requested dose is less than 0.3 milliliters

**OR**

**3.2** Both of the following:

**3.2.1** Physician attestation that in their clinical opinion the clinical response would be expected to be superior with Granix, Neupogen, Nivestym, Nypozi, or Releuko than experienced with Zarxio

**AND**

**3.2.2** One of the following:

- Failure to Zarxio as confirmed by claims history or submission of medical records
- History of intolerance, contraindication or adverse effect to Zarxio (please specify intolerance, contraindication or adverse effect)

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------|
| Product Name:Fulphila, Fylnetra, Nyvepria, Rolvedon, Stimufend, Ziextenzo                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                   |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Secondary Prophylaxis of Febrile Neutropenia (FN) |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 3 months or duration of therapy                   |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Prior Authorization                               |
| <p><b>Approval Criteria</b></p> <p><b>1 - ONE</b> of the following:</p> <p><b>1.1 BOTH</b> of the following:</p> <p><b>1.1.1 ONE</b> of the following:</p> <p><b>1.1.1.1</b> Patient is receiving myelosuppressive anticancer drug(s) given with a curative intent (curative chemotherapy, chemotherapy in curative adjuvant/neoadjuvant setting)</p> <p style="text-align: center;"><b>OR</b></p> <p><b>1.1.1.2</b> Patient is receiving myelosuppressive anticancer drug(s) with a non-curative intent and use of secondary prophylaxis is in accordance with the United States Food and Drug Administration approved labeling</p> <p style="text-align: center;"><b>OR</b></p> <p><b>1.1.1.3</b> Patient is receiving myelosuppressive anticancer drug(s) for definitive therapy (bridge to stem cell transplant, organ transplant, definitive surgery for oligometastatic disease)</p> |                                                   |

**AND**

**1.1.2** One of the following:

**1.1.2.1** Patient has a documented history of a neutropenic event (febrile neutropenia or low neutrophil count leading to delay of subsequent cycle) during a previous cycle of the same chemotherapy regimen at full dose for which primary prophylaxis was not received

**OR**

**1.1.2.2** Patient has a documented history of neutropenic event from a previous course of chemotherapy

**OR**

**1.2** One of the following:

**1.2.1** Both of the following:

**1.2.1.1** Patient is receiving myelosuppressive anticancer drug(s) given with non-curative intent

**AND**

**1.2.1.2** Patient has a documented history of neutropenic event (febrile neutropenia or low neutrophil count leading to delay of subsequent cycle) during a previous cycle of the same chemotherapy regimen after a trial of dose reduction

**OR**

**1.2.2** Patient is receiving myelosuppressive anticancer drug(s) where primary prophylaxis is indicated

**AND**

**2** - Prescribed by or in consultation with a hematologist or oncologist

**AND**

**3 - BOTH of the following:**

**3.1** Physician attestation that in their clinical opinion the clinical response would be expected to be superior with Fulphila, Fylnetra, Nyvepria, Rolvedon, Stimufend or Ziextenzo than experienced with Neulasta or Udenyca/Udenyca Onbody

**AND**

**3.2** One of the following:

- Failure to Neulasta or Udenyca/Udenyca Onbody as confirmed by claims history or submission of medical records
- History of intolerance, contraindication or adverse effect to Neulasta or Udenyca/Udenyca Onbody (please specify intolerance, contraindication or adverse effect)

|                                                                                                                                                                                                                                                                                           |                                       |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|
| Product Name:Leukine, Neulasta, Neulasta Onpro, Zarxio, Udenyca, Udenyca Onbody                                                                                                                                                                                                           |                                       |
| Diagnosis                                                                                                                                                                                                                                                                                 | Treatment of Febrile Neutropenia (FN) |
| Approval Length                                                                                                                                                                                                                                                                           | 1 month(s)                            |
| Guideline Type                                                                                                                                                                                                                                                                            | Prior Authorization                   |
| <p><b>Approval Criteria</b></p> <p><b>1 -</b> Diagnosis of febrile neutropenia (FN)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2 -</b> Patient has not received long-acting prophylactic pegfilgrastim in the last 14 days</p> <p style="text-align: center;"><b>AND</b></p> |                                       |

**3** - Patient has one or more risk factors for an infection-associated complication such as:

- Sepsis syndrome
- Greater than 65 years of age
- Absolute Neutrophil Count (ANC) less than 100/mcL
- Neutropenia expected to be greater than 10 days in duration
- Pneumonia
- Clinically documented infections including invasive fungal infection
- Hospitalization at the time of fever
- Prior episode(s) of FN

**AND**

**4** - Prescribed by or in consultation with a hematologist or oncologist

Product Name: Neupogen, Nivestym, Nypozi, Releuko

|           |                                       |
|-----------|---------------------------------------|
| Diagnosis | Treatment of Febrile Neutropenia (FN) |
|-----------|---------------------------------------|

|                 |            |
|-----------------|------------|
| Approval Length | 1 month(s) |
|-----------------|------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

### Approval Criteria

**1** - Diagnosis of febrile neutropenia (FN)

**AND**

**2** - Patient has not received long-acting prophylactic pegfilgrastim in the last 14 days

**AND**

**3** - Patient has one or more risk factors for an infection-associated complication such as:

- Sepsis syndrome
- Greater than 65 years of age
- Absolute Neutrophil Count (ANC) less than 100/mcL
- Neutropenia expected to be greater than 10 days in duration

- Pneumonia
- Clinically documented infections including invasive fungal infection
- Hospitalization at the time of fever
- Prior episode(s) of FN

**AND**

**4** - Prescribed by or in consultation with a hematologist or oncologist

**AND**

**5** - One of the following:

**5.1** The request is for Neupogen vial, Nivestym vial, or Releuko vial AND the requested dose is less than 0.3 milliliters

**OR**

**5.2** Both of the following:

**5.2.1** Physician attestation that in their clinical opinion the clinical response would be expected to be superior with Neupogen, Nivestym, Nypozi or Releuko than experienced with Zarxio

**AND**

**5.2.2** One of the following:

- Failure to Zarxio as confirmed by claims history or submission of medical records
- History of intolerance, contraindication or adverse effect to Zarxio (please specify intolerance, contraindication or adverse effect)

|                                                                           |                                       |
|---------------------------------------------------------------------------|---------------------------------------|
| Product Name:Fulphila, Fylnetra, Nyvepria, Rolvedon, Stimufend, Ziextenzo |                                       |
| Diagnosis                                                                 | Treatment of Febrile Neutropenia (FN) |
| Approval Length                                                           | 1 month(s)                            |
| Guideline Type                                                            | Prior Authorization                   |



**Approval Criteria**

**1** - Diagnosis of febrile neutropenia (FN)

**AND**

**2** - Patient has not received long-acting prophylactic pegfilgrastim in the last 14 days

**AND**

**3** - Patient has one or more risk factors for an infection-associated complication such as:

- Sepsis syndrome
- Greater than 65 years of age
- Absolute Neutrophil Count (ANC) less than 100/mcL
- Neutropenia expected to be greater than 10 days in duration
- Pneumonia
- Clinically documented infections including invasive fungal infection
- Hospitalization at the time of fever
- Prior episode(s) of FN

**AND**

**4** - Prescribed by or in consultation with a hematologist or oncologist

**AND**

**5** - Both of the following:

**5.1** Physician attestation that in their clinical opinion the clinical response would be expected to be superior with Fulphila, Fynetra, Nyvepria, Rolvedon, Stimufend or Ziextenzo than experienced with Neulasta or Udenyca/Udenyca Onbody

**AND**

**5.2** One of the following:

- Failure to Neulasta or Udenyca/Udenyca Onbody as confirmed by claims history or submission of medical records
- History of intolerance, contraindication or adverse effect to Neulasta or Udenyca/Udenyca Onbody (please specify intolerance, contraindication or adverse effect)

|                                                                                                                                                                                                                                                                                                                                                                            |                                  |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|
| Product Name:Zarxio                                                                                                                                                                                                                                                                                                                                                        |                                  |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                  | Severe Chronic Neutropenia (SCN) |
| Approval Length                                                                                                                                                                                                                                                                                                                                                            | 12 month(s)                      |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                             | Prior Authorization              |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of severe chronic neutropenia (SCN) [i.e., congenital, cyclic, and idiopathic neutropenias with chronic absolute neutrophil count (ANC) less than or equal to 500 neutrophils/microliter]</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Prescribed by or in consultation with a hematologist or oncologist</p> |                                  |

|                                                                                                                                                                                                                                                |                                  |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|
| Product Name:Neupogen, Nivestym, Nypozi, Releuko                                                                                                                                                                                               |                                  |
| Diagnosis                                                                                                                                                                                                                                      | Severe Chronic Neutropenia (SCN) |
| Approval Length                                                                                                                                                                                                                                | 12 month(s)                      |
| Guideline Type                                                                                                                                                                                                                                 | Prior Authorization              |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of severe chronic neutropenia (SCN) [i.e., congenital, cyclic, and idiopathic neutropenias with chronic absolute neutrophil count (ANC) less than or equal to 500 neutrophils/microliter]</p> |                                  |

**AND**

**2** - Prescribed by or in consultation with a hematologist or oncologist

**AND**

**3** - ONE of the following:

**3.1** The request is for Neupogen vial, Nivestym vial, or Releuko vial AND the requested dose is less than 0.3 milliliters

**OR**

**3.2** Both of the following:

**3.2.1** Physician attestation that in their clinical opinion the clinical response would be expected to be superior with Neupogen, Nivestym, Nypozi, or Releuko than experienced with Zarxio

**AND**

**3.2.2** One of the following:

- Failure to Zarxio as confirmed by claims history or submission of medical records
- History of intolerance, contraindication or adverse effect to Zarxio (please specify intolerance, contraindication or adverse effect)

|                                                                 |                                                    |
|-----------------------------------------------------------------|----------------------------------------------------|
| Product Name:Leukine, Neulasta, Zarxio, Udenyca, Udenyca Onbody |                                                    |
| Diagnosis                                                       | Hematopoietic Syndrome of Acute Radiation Syndrome |
| Approval Length                                                 | 3 months or duration of therapy                    |
| Guideline Type                                                  | Prior Authorization                                |
| <b>Approval Criteria</b>                                        |                                                    |

**1** - Patient has been acutely exposed to myelosuppressive doses of radiation

**AND**

**2** - Prescribed by or in consultation with a hematologist or oncologist

Product Name: Neupogen, Nivestym, Nypozi, Releuko

|           |                                                    |
|-----------|----------------------------------------------------|
| Diagnosis | Hematopoietic Syndrome of Acute Radiation Syndrome |
|-----------|----------------------------------------------------|

|                 |                                 |
|-----------------|---------------------------------|
| Approval Length | 3 months or duration of therapy |
|-----------------|---------------------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

### Approval Criteria

**1** - Patient has been acutely exposed to myelosuppressive doses of radiation

**AND**

**2** - Prescribed by or in consultation with a hematologist or oncologist

**AND**

**3** - ONE of the following:

**3.1** The request is for Neupogen vial, Nivestym vial, or Releuko vial AND the requested dose is less than 0.3 milliliters

**OR**

**3.2** Both of the following:

**3.2.1** Physician attestation that in their clinical opinion the clinical response would be expected to be superior with Neupogen, Nivestym, Nypozi, or Releuko than experienced with Zarxio

**AND**

**3.2.2** One of the following:

- Failure to Zarxio as confirmed by claims history or submission of medical records
- History of intolerance, contraindication or adverse effect to Zarxio (please specify intolerance, contraindication or adverse effect)

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                    |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------|
| Product Name:Fulphila, Fylnetra, Nyvepria, Rolvedon, Stimufend, Ziextenzo                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                    |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Hematopoietic Syndrome of Acute Radiation Syndrome |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 3 months or duration of therapy                    |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Prior Authorization                                |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Patient has been acutely exposed to myelosuppressive doses of radiation</p> <p><b>AND</b></p> <p><b>2</b> - Prescribed by or in consultation with a hematologist or oncologist</p> <p><b>AND</b></p> <p><b>3</b> - BOTH of the following:</p> <p><b>3.1</b> Physician attestation that in their clinical opinion the clinical response would be expected to be superior with Fulphila, Fylnetra, Nyvepria, Rolvedon, Stimufend or Ziextenzo than experienced with Neulasta or Udenyca/Udenyca Onbody</p> <p><b>AND</b></p> <p><b>3.2</b> One of the following:</p> |                                                    |

- Failure to Neulasta or Udenyca/Udenyca Onbody as confirmed by claims history or submission of medical records
- History of intolerance, contraindication or adverse effect to Neulasta or Udenyca/Udenyca Onbody (please specify intolerance, contraindication or adverse effect)

## 2 . Revision History

| Date      | Notes                             |
|-----------|-----------------------------------|
| 2/20/2025 | Updated formularies. Added Nypozi |

Combination Basal Insulin/GLP-1 Receptor Agonist



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-242252                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Guideline Name</b> | Combination Basal Insulin/GLP-1 Receptor Agonist                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 7/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                      |                     |
|----------------------|---------------------|
| Product Name:Soliqua |                     |
| Approval Length      | 12 month(s)         |
| Guideline Type       | Prior Authorization |
| Approval Criteria    |                     |

**1** - Submission of medical records (e.g., chart notes) confirming diagnosis of type 2 diabetes mellitus as evidenced by ONE of the following laboratory values:

- A1C greater than or equal to 6.5%
- Fasting plasma glucose (FPG) greater than or equal to 126 mg/dL
- 2-hour plasma glucose (PG) greater than or equal to 200 mg/dL during oral glucose tolerance test
- Random plasma glucose greater than or equal to 200 mg/dL in patient with classic symptoms of hyperglycemia or hyperglycemic crisis

**OR**

**2** - For patients requiring ongoing treatment for type 2 diabetes mellitus (i.e., diagnosed greater than 2 years ago), submission of medical records (e.g., chart notes) confirming diagnosis of type 2 diabetes mellitus

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                       |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Xultophy                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                       |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - ONE of the following:</p> <p><b>1.1</b> Submission of medical records (e.g., chart notes) confirming diagnosis of type 2 diabetes mellitus as evidenced by ONE of the following laboratory values:</p> <ul style="list-style-type: none"> <li>• A1C greater than or equal to 6.5%</li> <li>• Fasting plasma glucose (FPG) greater than or equal to 126 mg/dL</li> <li>• 2-hour plasma glucose (PG) greater than or equal to 200 mg/dL during oral glucose tolerance test</li> <li>• Random plasma glucose greater than or equal to 200 mg/dL in patient with classic symptoms of hyperglycemia or hyperglycemic crisis</li> </ul> <p style="text-align: center;"><b>OR</b></p> <p><b>1.2</b> For patients requiring ongoing treatment for type 2 diabetes mellitus (i.e., diagnosed</p> |                       |



greater than 2 years ago), submission of medical records (e.g., chart notes) confirming diagnosis of type 2 diabetes mellitus

**AND**

**2** - Suboptimal response (i.e., suboptimal glycemic control) to ONE of the following, for a minimum of 90 days, as confirmed by claims history or submission of medical records:

- GLP-1 (glucagon-like peptide-1) receptor agonist [e.g., Victoza (liraglutide injection), Ozempic (semaglutide), Rybelsus (semaglutide)]
- Basal insulin (e.g., insulin glargine, insulin degludec, insulin detemir)

**AND**

**3** - ONE of the following:

- Failure to Soliqua, after a minimum of 90 days of therapy, as confirmed by claims history or submission of medical records
- History of contraindication or intolerance to Soliqua (please specify contraindication or intolerance)

|                                                                                                        |                     |
|--------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Xultophy                                                                                  |                     |
| Approval Length                                                                                        | 12 month(s)         |
| Therapy Stage                                                                                          | Reauthorization     |
| Guideline Type                                                                                         | Prior Authorization |
| <b>Approval Criteria</b><br><b>1</b> - Documentation of positive clinical response to Xultophy therapy |                     |

## 2 . Revision History

| Date | Notes |
|------|-------|
|------|-------|

|           |                                                                                                        |
|-----------|--------------------------------------------------------------------------------------------------------|
| 4/23/2025 | Updated formularies. Updated diagnosis and step therapy language.<br>Removed step therapy from Soliqua |
|-----------|--------------------------------------------------------------------------------------------------------|

Cometriq



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-356192                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Guideline Name</b> | Cometriq                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 9/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                       |                       |
|-----------------------|-----------------------|
| Product Name:Cometriq |                       |
| Diagnosis             | Thyroid Carcinoma     |
| Approval Length       | 12 month(s)           |
| Therapy Stage         | Initial Authorization |

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Prior Authorization |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1 - Diagnosis of medullary carcinoma</b></p> <p style="text-align: center;"><b>OR</b></p> <p><b>2 - ALL of the following:</b></p> <p><b>2.1 Diagnosis of ONE of the following:</b></p> <ul style="list-style-type: none"> <li>• Follicular carcinoma</li> <li>• Oncocytic cell carcinoma</li> <li>• Papillary carcinoma</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>2.2 Disease is progressive after treatment with ONE of the following as confirmed by claims history or submission of medical records:</b></p> <ul style="list-style-type: none"> <li>• Lenvima (lenvatinib)</li> <li>• Nexavar (sorafenib)</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>2.3 Disease is at least ONE of the following:</b></p> <ul style="list-style-type: none"> <li>• Symptomatic iodine-refractory</li> <li>• Unresectable locoregional recurrent or persistent disease</li> <li>• Distant metastatic disease</li> </ul> |                     |

|                       |                   |
|-----------------------|-------------------|
| Product Name:Cometriq |                   |
| Diagnosis             | Thyroid Carcinoma |
| Approval Length       | 12 month(s)       |
| Therapy Stage         | Reauthorization   |

|                                                                                                                        |                     |
|------------------------------------------------------------------------------------------------------------------------|---------------------|
| Guideline Type                                                                                                         | Prior Authorization |
| <b>Approval Criteria</b><br><b>1 - Patient does not show evidence of progressive disease while on Cometriq therapy</b> |                     |

|                                                                                                                                                                                             |                                    |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|
| Product Name:Cometriq                                                                                                                                                                       |                                    |
| Diagnosis                                                                                                                                                                                   | Non-Small Cell Lung Cancer (NSCLC) |
| Approval Length                                                                                                                                                                             | 12 month(s)                        |
| Therapy Stage                                                                                                                                                                               | Initial Authorization              |
| Guideline Type                                                                                                                                                                              | Prior Authorization                |
| <b>Approval Criteria</b><br><b>1 - Diagnosis of non-small cell lung cancer (NSCLC)</b><br><br><p style="text-align: center;"><b>AND</b></p> <b>2 - Positive for RET gene rearrangements</b> |                                    |

|                                                                                                                        |                                    |
|------------------------------------------------------------------------------------------------------------------------|------------------------------------|
| Product Name:Cometriq                                                                                                  |                                    |
| Diagnosis                                                                                                              | Non-Small Cell Lung Cancer (NSCLC) |
| Approval Length                                                                                                        | 12 month(s)                        |
| Therapy Stage                                                                                                          | Reauthorization                    |
| Guideline Type                                                                                                         | Prior Authorization                |
| <b>Approval Criteria</b><br><b>1 - Patient does not show evidence of progressive disease while on Cometriq therapy</b> |                                    |

|                                                                                                                                                |                           |
|------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Cometriq                                                                                                                          |                           |
| Diagnosis                                                                                                                                      | NCCN Recommended Regimens |
| Approval Length                                                                                                                                | 12 month(s)               |
| Therapy Stage                                                                                                                                  | Initial Authorization     |
| Guideline Type                                                                                                                                 | Prior Authorization       |
| <b>Approval Criteria</b><br><br><b>1</b> - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium |                           |

|                                                                                                            |                           |
|------------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Cometriq                                                                                      |                           |
| Diagnosis                                                                                                  | NCCN Recommended Regimens |
| Approval Length                                                                                            | 12 month(s)               |
| Therapy Stage                                                                                              | Reauthorization           |
| Guideline Type                                                                                             | Prior Authorization       |
| <b>Approval Criteria</b><br><br><b>1</b> - Documentation of positive clinical response to Cometriq therapy |                           |

## 2 . Revision History

| Date      | Notes                                                  |
|-----------|--------------------------------------------------------|
| 7/31/2025 | Combined formularies. No changes to clinical criteria. |

Compounds and Bulk Powders



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-369223                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Guideline Name</b> | Compounds and Bulk Powders                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Florida MMA (CSFL, CSFLD)</li> <li>• Medicaid - Community &amp; State Louisiana (ACULA, ACULAC)</li> <li>• Medicaid - Community &amp; State Michigan (ACUMI)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State North Carolina (ACUNC)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Washington (ACUWA, ACUWAAHE, ACUWAC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State Pennsylvania (ACUPA)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 10/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|
| Product Name:Compounds or Bulk Powders                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | 12 month(s)    |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Administrative |
| <p><b>Approval Criteria</b></p> <p>1 - The request is for compounded oral budesonide for the treatment of eosinophilic esophagitis*</p> <p style="text-align: center;"><b>OR</b></p> <p>2 - ALL of the following:</p> <p>2.1 The requested drug component is a covered medication</p> <p style="text-align: center;"><b>AND</b></p> <p>2.2 ONE of the following:</p> <p>2.2.1 The requested drug component is to be administered for an FDA (Food and Drug Administration)-approved indication</p> <p style="text-align: center;"><b>OR</b></p> <p>2.2.2 The use of this drug is supported by information from ONE of the following appropriate compendia of current literature:</p> <ul style="list-style-type: none"> <li>• American Hospital Formulary Service Drug Information</li> <li>• National Comprehensive Cancer Network Drugs and Biologics Compendium</li> <li>• Thomson Micromedex DrugDex</li> <li>• Clinical pharmacology</li> <li>• United States Pharmacopoeia-National Formulary (USP-NF)</li> </ul> <p style="text-align: center;"><b>AND</b></p> |                |



**2.3** If a drug included in the compound requires prior authorization and/or step therapy, all drug specific clinical criteria must also be met

**AND**

**2.4** If the drug component is no longer available commercially, it must not have been withdrawn for safety reasons

**AND**

**2.5** ONE of the following:

- A unique vehicle is required
- A unique dosage form is required for a commercially available product due to patient's age, weight, or inability to take a solid dosage form
- A unique formulation is required for a commercially available product due to an allergy or intolerance to an inactive ingredient in the commercially available product
- There is a shortage of the commercially available product per the FDA Drug Shortage database or the ASHP (American Society of Health-System Pharmacists) Current Drug Shortages tracking log

**AND**

**2.6** Coverage for compounds and bulk powders will NOT be approved for any of the following:

**2.6.1** For topical compound preparations (e.g., creams, ointments, lotions, or gels to be applied to the skin for transdermal, transcutaneous, or any other topical route), if the requested compound contains any FDA approved ingredient that is not FDA approved for TOPICAL use (see Table 1 in Background section)

**OR**

**2.6.2** If the requested compound contains topical fluticasone, topical fluticasone will NOT be approved unless both of the following are met:

**2.6.2.1** Topical fluticasone is intended to treat a dermatologic condition (scar treatments are considered cosmetic and will not be covered)

**AND**

**2.6.2.2** Patient has a contraindication to all commercially available topical fluticasone formulations

**OR**

**2.6.3** Requested compound contains any ingredients when used for cosmetic purposes (see Table 2 in Background section)

**OR**

**2.6.4** Requested compound contains any ingredient(s) which are on the FDA's Do Not Compound List (see Table 3 in Background section)

Notes

\*All other indications for budesonide refer to criteria in step 2

## 2 . Background

### Benefit/Coverage/Program Information

**Table 1: Example topical compound preparations that contain any FDA approved ingredient that are not FDA approved for TOPICAL use, including but NOT LIMITED TO the following:**

- (1) Ketamine
- (2) Gabapentin
- (3) Flurbiprofen (topical ophthalmic use not included)
- (4) Ketoprofen
- (5) Morphine
- (6) Nabumetone

- (7) Oxycodone
- (8) Cyclobenzaprine
- (9) Baclofen
- (10) Tramadol
- (11) Hydrocodone
- (12) Meloxicam
- (13) Amitriptyline
- (14) Pentoxifylline
- (15) Orphenadrine
- (16) Piroxicam
- (17) Levocetirizine
- (18) Amantadine
- (19) Oxytocin
- (20) Sumatriptan
- (21) Chorionic gonadotropin (human)
- (22) Clomipramine
- (23) Dexamethasone
- (24) Hydromorphone
- (25) Methadone
- (26) Papaverine
- (27) Mefenamic acid
- (28) Promethazine

- (29) Succimer DMSA
- (30) Tizanidine
- (31) Apomorphine
- (32) Carbamazepine
- (33) Ketorolac
- (34) Dimercaptopropane-sulfonate
- (35) Dimercaptosuccinic acid
- (36) Duloxetine
- (37) Fluoxetine
- (38) Bromfenac (topical ophthalmic use not included)
- (39) Nepafenac (topical ophthalmic use not included)

**Table 2: Example compounds that contain ingredients for cosmetic purposes:**

- (1) Hydroquinone
- (2) Acetyl hexapeptide-8
- (3) Tocopheryl Acid Succinate
- (4) PracaSil TM-Plus
- (5) Chrysaderm Day Cream
- (6) Chrysaderm Night Cream
- (7) PCCA Spira-Wash
- (8) Lipopen Ultra
- (9) Versapro

- (10) Fluticasone
- (11) Mometasone
- (12) Halobetasol
- (13) Betamethasone
- (14) Clobetasol
- (15) Triamcinolone
- (16) Minoxidil
- (17) Tretinoin
- (18) Dexamethasone
- (19) Spironolactone
- (20) Cycloserine
- (21) Tamoxifen
- (22) Sermorelin
- (23) Mederma Cream
- (24) PCCA Cosmetic HRT Base
- (25) Sanare Scar Therapy Cream
- (26) Scarcin Cream
- (27) Apothederm
- (28) Stera Cream
- (29) Copasil
- (30) Collagenase
- (31) Arbutin Alpha

- (32) Nourisil
- (33) Freedom Cepapro
- (34) Freedom Silomac Andydrous
- (35) Retinaldehyde
- (36) Apothederm

**Table 3: Example ingredients on the FDA's Do Not Compound List:**

- (1) 3,3',4',5-tetrachlorosalicylanilide
- (2) Adenosine phosphate
- (3) Adrenal cortex
- (4) Alatrofloxacin mesylate
- (5) Aminopyrine
- (6) Astemizole
- (7) Azaribine
- (8) Benoxaprofen
- (9) Bithionol
- (10) Camphorated oil
- (11) Carbetapentane citrate
- (12) Casein, iodinated
- (13) Cerivastatin sodium
- (14) Chlormadinone acetate
- (15) Chloroform

- (16) Cisapride
- (17) Defenfluramine hydrochloride
- (18) Diamthazole dihydrochloride
- (19) Dibromsalan
- (20) Dihydrostreptomycin sulfate
- (21) Dipyrone
- (22) Encainide hydrochloride
- (23) Etretinate
- (24) Fenfluramine hydrochloride
- (25) Flosequinan
- (26) Glycerol, iodinated
- (27) Grepafloxacin
- (28) Mepazine
- (29) Metabromsalan
- (30) Methapyrilene
- (31) Methopholine
- (32) Methoxyflurane
- (33) Mibefradil dihydrochloride
- (34) Nomifensine maleate
- (35) Novobiocin sodium
- (36) Oxyphenisatin acetate
- (37) Oxyphenisatin

- (38) Pemoline
- (39) Pergolide mesylate
- (40) Phenacetin
- (41) Phenformin hydrochloride
- (42) Phenylpropanolamine
- (43) Pipamazine
- (44) Potassium arsenite
- (45) Propoxyphene
- (46) Rapacuronium bromide
- (47) Rofecoxib
- (48) Sibutramine hydrochloride
- (49) Sparteine sulfate
- (50) Sulfadimethoxine
- (51) Sweet spirits of nitre
- (52) Tegaserod maleate
- (53) Temafloxacin hydrochloride
- (54) Terfenadine
- (55) Ticrynafen
- (56) Tribromsalan
- (57) Trichloroethane
- (58) Troglitazone
- (59) Trovafloxacin mesylate:



(60) Urethane

(61) Valdecoxib

(62) Zomepirac sodium

### 3 . Revision History

| Date      | Notes                                                                 |
|-----------|-----------------------------------------------------------------------|
| 8/14/2025 | Added LA to formularies, no clinical changes to criteria for 10/1/25. |

Constipation Agents



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-373465                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Guideline Name</b> | Constipation Agents                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 10/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                                   |                       |
|-----------------------------------|-----------------------|
| Product Name:generic lubiprostone |                       |
| Approval Length                   | 12 month(s)           |
| Therapy Stage                     | Initial Authorization |
| Guideline Type                    | Prior Authorization   |
| Approval Criteria                 |                       |

**1 - ONE of the following:**

**1.1** Diagnosis of opioid-induced constipation in an adult with chronic, non-cancer pain

**OR**

**1.2** Diagnosis of opioid-induced constipation in a patient with chronic pain related to prior cancer diagnosis or its treatment who does not require frequent (e.g., weekly) opioid dosage escalation

**OR**

**1.3** Diagnosis of chronic idiopathic constipation

**OR**

**1.4 BOTH of the following:**

- Diagnosis of irritable bowel syndrome with constipation
- Patient was female at birth

**AND**

**2 - ONE of the following:**

**2.1** Failure to ONE of the following as confirmed by claims history or submission of medical records:

- Lactulose
- Polyethylene glycol (Miralax)

**OR**

**2.2** History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- Lactulose

- Polyethylene glycol (Miralax)

|                             |                       |
|-----------------------------|-----------------------|
| Product Name: Brand Amitiza |                       |
| Approval Length             | 12 month(s)           |
| Therapy Stage               | Initial Authorization |
| Guideline Type              | Prior Authorization   |

**Approval Criteria**

1 - For diagnosis of opioid-induced constipation (OIC), BOTH of the following:

1.1 ONE of the following:

- Diagnosis of OIC in an adult with chronic, non-cancer pain
- Diagnosis of OIC in a patient with chronic pain related to prior cancer diagnosis or its treatment who does not require frequent (e.g., weekly) opioid dosage escalation

**AND**

1.2 ONE of the following:

1.2.1 Failure to ALL of the following as confirmed by claims history or submission of medical records:

- Lactulose or polyethylene glycol (Miralax)
- Movantik
- Lubiprostone (generic of Amitiza)

**OR**

1.2.2 History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication):

- Lactulose
- Polyethylene glycol (Miralax)
- Movantik
- Lubiprostone (generic of Amitiza)

**OR**

**2** - For diagnosis of chronic idiopathic constipation, **ONE** of the following:

**2.1** Failure to **ALL** of the following as confirmed by claims history or submission of medical records:

- Lactulose or polyethylene glycol (Miralax)
- Prucalopride (generic of Motegrity)
- Lubiprostone (generic of Amitiza)

**OR**

**2.2** History of intolerance or contraindication to **ALL** of the following (please specify intolerance or contraindication):

- Lactulose
- Polyethylene glycol (Miralax)
- Prucalopride (generic of Motegrity)
- Lubiprostone (generic of Amitiza)

**OR**

**3** - For diagnosis of irritable bowel syndrome with constipation (IBS-C), **BOTH** of the following:

**3.1** Patient was female at birth

**AND**

**3.2** **ONE** of the following:

**3.2.1** Failure to **BOTH** of the following as confirmed by claims history or submission of medical records:

- Lactulose or polyethylene glycol (Miralax)
- Lubiprostone (generic of Amitiza)

**OR**

**3.2.2** History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication):

- Lactulose
- Polyethylene glycol (Miralax)
- Lubiprostone (generic of Amitiza)

|                       |                       |
|-----------------------|-----------------------|
| Product Name: Linzess |                       |
| Approval Length       | 12 month(s)           |
| Therapy Stage         | Initial Authorization |
| Guideline Type        | Prior Authorization   |

**Approval Criteria**

**1** - For diagnosis of chronic idiopathic constipation, ONE of the following:

**1.1** Failure to ALL of the following as confirmed by claims history or submission of medical records:

- Lactulose or polyethylene glycol (Miralax)
- Prucalopride (generic of Motegrity)
- Lubiprostone (generic of Amitiza)

**OR**

**1.2** History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication):

- Lactulose
- Polyethylene glycol (Miralax)
- Prucalopride (generic of Motegrity)
- Lubiprostone (generic of Amitiza)

**OR**

**2** - For diagnosis of irritable bowel syndrome with constipation (IBS-C), ONE of the following:

**2.1** Failure to BOTH of the following as confirmed by claims history or submission of medical records:

- Lactulose or polyethylene glycol (Miralax)
- Lubiprostone (generic of Amitiza)

**OR**

**2.2** History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication):

- Lactulose
- Polyethylene glycol (Miralax)
- Lubiprostone (generic of Amitiza)

**OR**

**3** - For diagnosis of functional constipation, ONE of the following:

**3.1** Failure to ONE of the following as confirmed by claims history or submission of medical records:

- Lactulose
- Polyethylene glycol (Miralax)

**OR**

**3.2** History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- Lactulose
- Polyethylene glycol (Miralax)

|                       |                       |
|-----------------------|-----------------------|
| Product Name:Trulance |                       |
| Approval Length       | 12 month(s)           |
| Therapy Stage         | Initial Authorization |
| Guideline Type        | Prior Authorization   |

## **Approval Criteria**

**1** - For diagnosis of chronic idiopathic constipation, ONE of the following:

**1.1** Failure to ALL of the following as confirmed by claims history or submission of medical records:

- Lactulose or polyethylene glycol (Miralax)
- Prucalopride (generic of Motegrity)
- Lubiprostone (generic of Amitiza)

**OR**

**1.2** History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication):

- Lactulose
- Polyethylene glycol (Miralax)
- Prucalopride (generic of Motegrity)
- Lubiprostone (generic of Amitiza)

**OR**

**2** - For diagnosis of irritable bowel syndrome with constipation (IBS-C), ONE of the following:

**2.1** Failure to BOTH of the following as confirmed by claims history or submission of medical records:

- Lactulose or polyethylene glycol (Miralax)
- Lubiprostone (generic of Amitiza)

**OR**

**2.2** History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication):

- Lactulose
- Polyethylene glycol (Miralax)
- Lubiprostone (generic of Amitiza)



|                                                     |                       |
|-----------------------------------------------------|-----------------------|
| Product Name: Brand Motegrity, generic prucalopride |                       |
| Approval Length                                     | 12 month(s)           |
| Therapy Stage                                       | Initial Authorization |
| Guideline Type                                      | Prior Authorization   |

  

**Approval Criteria**

1 - Diagnosis of chronic idiopathic constipation

**AND**

2 - ONE of the following:

2.1 Failure to ONE of the following as confirmed by claims history or submission of medical records:

- Lactulose
- Polyethylene glycol (Miralax)

**OR**

2.2 History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- Lactulose
- Polyethylene glycol (Miralax)

**AND**

3 - ONE of the following:

- Failure to lubiprostone (generic of Amitiza) as confirmed by claims history or submission of medical records
- History of intolerance or contraindication to lubiprostone (generic of Amitiza) (please specify intolerance or contraindication)

|                        |                       |
|------------------------|-----------------------|
| Product Name: Movantik |                       |
| Approval Length        | 12 month(s)           |
| Therapy Stage          | Initial Authorization |
| Guideline Type         | Prior Authorization   |

  

**Approval Criteria**

**1 - ONE of the following:**

- Diagnosis of opioid-induced constipation in a patient being treated for chronic, non-cancer pain
- Diagnosis of opioid-induced constipation in a patient with chronic pain related to prior cancer diagnosis or its treatment who does not require frequent (e.g., weekly) opioid dosage escalation

**AND**

**2 - ONE of the following:**

**2.1** Failure to ONE of the following as confirmed by claims history or submission of medical records:

- Lactulose
- Polyethylene glycol (Miralax)

**OR**

**2.2** History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- Lactulose
- Polyethylene glycol (Miralax)

**AND**

**3 - ONE of the following:**

- Failure to lubiprostone (generic of Amitiza) as confirmed by claims history or submission of medical records

- History of intolerance or contraindication to lubiprostone (generic of Amitiza) (please specify intolerance or contraindication)

|                                          |                       |
|------------------------------------------|-----------------------|
| Product Name: Symproic, Relistor Tablets |                       |
| Approval Length                          | 12 month(s)           |
| Therapy Stage                            | Initial Authorization |
| Guideline Type                           | Prior Authorization   |

**Approval Criteria**

1 - ONE of the following:

- Diagnosis of opioid-induced constipation in a patient being treated for chronic, non-cancer pain
- Diagnosis of opioid-induced constipation in a patient with chronic pain related to prior cancer diagnosis or its treatment who does not require frequent (e.g., weekly) opioid dosage escalation

**AND**

2 - ONE of the following:

**2.1** Failure to ONE of the following as confirmed by claims history or submission of medical records:

- Lactulose
- Polyethylene glycol (Miralax)

**OR**

**2.2** History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- Lactulose
- Polyethylene glycol (Miralax)

**AND**

**3 - ONE of the following:**

**3.1** Failure to BOTH of the following as confirmed by claims history or submission of medical records:

- Lubiprostone (generic of Amitiza)
- Movantik

**OR**

**3.2** History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- Lubiprostone (generic of Amitiza)
- Movantik

|                                                                                                                                                                                                                                                                                                                                                                                                                 |                       |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Relistor injection                                                                                                                                                                                                                                                                                                                                                                                 |                       |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                 | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                   | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                  | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1 -</b> Diagnosis of opioid induced constipation in patients with advanced illness receiving palliative care</p> <p style="text-align: center;"><b>OR</b></p> <p><b>2 - BOTH of the following:</b></p> <p><b>2.1 ONE of the following:</b></p> <ul style="list-style-type: none"> <li>• Diagnosis of opioid induced constipation with chronic, non-cancer pain</li> </ul> |                       |

- Diagnosis of opioid induced constipation in patients with chronic pain related to prior cancer or cancer treatment who do not require frequent (e.g., weekly) opioid dosage escalation

**AND**

**2.2 ONE of the following:**

**2.2.1** The patient is not able to swallow oral medications

**OR**

**2.2.2** Failure to ALL of the following as confirmed by claims history or submitted medical records:

- Lactulose OR polyethylene glycol (Miralax)
- Lubiprostone (generic of Amitiza)
- Movantik

**OR**

**2.2.3** History of contraindication or intolerance to ALL of the following (please specify intolerance or contraindication):

- Lactulose
- Polyethylene glycol (Miralax)
- Lubiprostone (generic of Amitiza)
- Movantik

|                      |                       |
|----------------------|-----------------------|
| Product Name:Zelnorm |                       |
| Approval Length      | 12 month(s)           |
| Therapy Stage        | Initial Authorization |
| Guideline Type       | Prior Authorization   |
| Approval Criteria    |                       |

**1 - Diagnosis of irritable bowel syndrome with constipation**

**AND**

**2 - Patient was female at birth**

**AND**

**3 - ONE of the following:**

**3.1** Failure to ONE of the following as confirmed by claims history or submission of medical records:

- Lactulose
- Polyethylene glycol (Miralax)

**OR**

**3.2** History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- Lactulose
- Polyethylene glycol (Miralax)

**AND**

**4 - ONE of the following:**

- Failure to lubiprostone (generic of Amitiza) as confirmed by claims history or submission of medical records
- History of intolerance or contraindication to lubiprostone (generic of Amitiza) (please specify intolerance or contraindication)

|                      |                       |
|----------------------|-----------------------|
| Product Name:lbsrela |                       |
| Approval Length      | 12 month(s)           |
| Therapy Stage        | Initial Authorization |

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Prior Authorization |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1 - Diagnosis of irritable bowel syndrome with constipation</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>2 - ONE of the following:</b></p> <p><b>2.1 Failure to ONE of the following as confirmed by claims history or submission of medical records:</b></p> <ul style="list-style-type: none"> <li>• Lactulose</li> <li>• Polyethylene glycol (Miralax)</li> </ul> <p style="text-align: center;"><b>OR</b></p> <p><b>2.2 History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):</b></p> <ul style="list-style-type: none"> <li>• Lactulose</li> <li>• Polyethylene glycol (Miralax)</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>3 - ONE of the following:</b></p> <ul style="list-style-type: none"> <li>• Failure to lubiprostone (generic of Amitiza) as confirmed by claims history or submission of medical records</li> <li>• History of intolerance or contraindication to lubiprostone (generic of Amitiza) (please specify intolerance or contraindication)</li> </ul> |                     |

|                                                                                                                                                                      |                 |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|
| Product Name: Brand Amitiza, generic lubiprostone, Ibsrela, Linzess, Brand Motegrity, generic prucalopride, Movantik, Symproic, Trulance, Zelnorm, Relistor tabs/inj |                 |
| Approval Length                                                                                                                                                      | 12 month(s)     |
| Therapy Stage                                                                                                                                                        | Reauthorization |

|                                                                                               |                     |
|-----------------------------------------------------------------------------------------------|---------------------|
| Guideline Type                                                                                | Prior Authorization |
| <b>Approval Criteria</b><br><b>1</b> - Documentation of positive clinical response to therapy |                     |

## 2 . Revision History

| Date      | Notes                                          |
|-----------|------------------------------------------------|
| 8/27/2025 | Added Relistor. GL restructured for efficiency |



Continuous Glucose Monitors



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-450194                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Guideline Name</b> | Continuous Glucose Monitors                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Michigan (ACUMI)</li> <li>• Medicaid - Community &amp; State Washington (ACUWA, ACUWAAHE, ACUWAC)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 12/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                                                                                  |                       |
|----------------------------------------------------------------------------------|-----------------------|
| Product Name:Continuous Glucose Monitors, sensors, and transmitters (all brands) |                       |
| Approval Length                                                                  | 12 month(s)           |
| Therapy Stage                                                                    | Initial Authorization |
| Guideline Type                                                                   | Prior Authorization   |

**Approval Criteria**

**1** - Diagnosis of diabetes

**AND**

**2** - One of the following:

**2.1** Patient is on an intensive insulin regimen (3 or more insulin injections per day or uses continuous subcutaneous insulin infusion pump)

**OR**

**2.2** One of the following:

**2.2.1** Patient has a history of a level 3 hypoglycemic event [glucose less than 54mg/dL (3.0mmol/L)] characterized by altered mental and/or physical state requiring third-party assistance for treatment of hypoglycemia

**OR**

**2.2.2** Patient has a history of more than one level 2 hypoglycemia event [glucose less than 54mg/dL (3.0mmol/L)] that persist despite multiple attempts to adjust medication(s) or modify diabetes treatment plan

**AND**

**3** - Patient regularly monitors blood glucose 4 or more times per day

**AND**

**4** - If the request is for a non-preferred continuous glucose monitor (all components), ONE of the following:

**4.1** BOTH of the following:

- Patient has a physical or mental limitation that makes utilization of Dexcom G6 and Dexcom G7 unsafe, inaccurate, or otherwise not feasible (e.g., manual dexterity) (document limitation)
- Patient has a physical or mental limitation that makes utilization of the preferred Freestyle Libre product unsafe, inaccurate, or otherwise not feasible (e.g., manual dexterity) (document limitation)

**OR**

**4.2** Provider submits documentation why the patient requires use of a non-preferred continuous glucose monitor system for treatment of diabetes, rather than one of the preferred products

| Product Name:Continuous Glucose Monitors, sensors, and transmitters (all brands) |                     |
|----------------------------------------------------------------------------------|---------------------|
| Approval Length                                                                  | 12 month(s)         |
| Therapy Stage                                                                    | Reauthorization     |
| Guideline Type                                                                   | Prior Authorization |
| <b>Approval Criteria</b><br><br>1 - Documentation of positive clinical response  |                     |

## 2 . Revision History

| Date       | Notes                                                                                                                                   |
|------------|-----------------------------------------------------------------------------------------------------------------------------------------|
| 11/10/2025 | Updated GPI. Updated criteria to add definitions to hypoglycemia and make reference to all "NP" products, instead of specific products. |

Copiktra



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-363190                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Guideline Name</b> | Copiktra                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 9/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                       |                                                                       |
|-----------------------|-----------------------------------------------------------------------|
| Product Name:Copiktra |                                                                       |
| Diagnosis             | Chronic Lymphocytic Leukemia (CLL) / Small Lymphocytic Lymphoma (SLL) |
| Approval Length       | 12 month(s)                                                           |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                       |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Disease is relapsed or refractory</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - ONE of the following:</p> <p><b>3.1</b> Failure to at least TWO prior therapies for CLL/SLL confirmed by claims history or submitted medical records. Examples include, but not limited to, regimens consisting of: [Leukeran (chlorambucil), Gazyva (obinutuzumab), Arzerra (ofatumumab), Bendeka (bendamustine), Imbruvica (ibrutinib), Calquence (acalabrutinib), Venclexta (venetoclax), etc.]</p> <p style="text-align: center;"><b>OR</b></p> <p><b>3.2</b> History of intolerance or contraindication to at least TWO prior therapies for CLL/SLL. Examples include, but not limited to, regimens consisting of: [Leukeran (chlorambucil), Gazyva (obinutuzumab), Arzerra (ofatumumab), Bendeka (bendamustine), Imbruvica (ibrutinib), Calquence (acalabrutinib), Venclexta (venetoclax), etc.] (please specify intolerance or contraindication)</p> |                       |

|                        |                       |
|------------------------|-----------------------|
| Product Name: Copiktra |                       |
| Diagnosis              | T-cell Lymphomas      |
| Approval Length        | 12 month(s)           |
| Therapy Stage          | Initial Authorization |
| Guideline Type         | Prior Authorization   |

### Approval Criteria

**1** - For diagnosis of Hepatosplenic T-cell lymphoma, ALL of the following:

**1.1** Disease is relapsed or refractory

**AND**

**1.2** ONE of the following:

- Failure to at least two prior systemic therapies confirmed by claims history or submitted medical records
- History of intolerance or contraindication to at least two prior systemic therapies (please specify intolerance or contraindication)

**OR**

**2** - For diagnosis of Breast implant-associated anaplastic large cell lymphoma, ALL of the following:

- Disease is relapsed or refractory
- Used as second-line and subsequent therapy

**OR**

**3** - For diagnosis of Peripheral T-cell lymphoma, ONE of the following:

- Used as initial palliative intent therapy
- Used as second-line and subsequent therapy

| Product Name: Copiktra |                                                                                         |
|------------------------|-----------------------------------------------------------------------------------------|
| Diagnosis              | Chronic Lymphocytic Leukemia (CLL) / Small Lymphocytic Lymphoma (SLL), T-cell Lymphomas |
| Approval Length        | 12 month(s)                                                                             |
| Therapy Stage          | Reauthorization                                                                         |

|                                                                                                                        |                     |
|------------------------------------------------------------------------------------------------------------------------|---------------------|
| Guideline Type                                                                                                         | Prior Authorization |
| <b>Approval Criteria</b><br><b>1</b> - Patient does not show evidence of progressive disease while on Copiktra therapy |                     |

|                                                                                                                                            |                           |
|--------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Copiktra                                                                                                                      |                           |
| Diagnosis                                                                                                                                  | NCCN Recommended Regimens |
| Approval Length                                                                                                                            | 12 month(s)               |
| Therapy Stage                                                                                                                              | Initial Authorization     |
| Guideline Type                                                                                                                             | Prior Authorization       |
| <b>Approval Criteria</b><br><b>1</b> - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium |                           |

|                                                                                                        |                           |
|--------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Copiktra                                                                                  |                           |
| Diagnosis                                                                                              | NCCN Recommended Regimens |
| Approval Length                                                                                        | 12 month(s)               |
| Therapy Stage                                                                                          | Reauthorization           |
| Guideline Type                                                                                         | Prior Authorization       |
| <b>Approval Criteria</b><br><b>1</b> - Documentation of positive clinical response to Copiktra therapy |                           |

## 2 . Revision History

|      |       |
|------|-------|
| Date | Notes |
|------|-------|

|           |                               |
|-----------|-------------------------------|
| 8/11/2025 | Updated formularies to add IN |
|-----------|-------------------------------|



Copper Chelating Agents



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-354250                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Guideline Name</b> | Copper Chelating Agents                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Pennsylvania (ACUPA)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 9/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                                                                    |                                    |
|--------------------------------------------------------------------|------------------------------------|
| Product Name: Brand Depen Titratabs, generic penicillamine tablets |                                    |
| Diagnosis                                                          | Severe active rheumatoid arthritis |
| Approval Length                                                    | 12 month(s)                        |

|                                                                                        |                       |
|----------------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                          | Initial Authorization |
| Guideline Type                                                                         | Prior Authorization   |
| <b>Approval Criteria</b><br><b>1 - Diagnosis of severe active rheumatoid arthritis</b> |                       |

|                                                                                               |                                    |
|-----------------------------------------------------------------------------------------------|------------------------------------|
| Product Name:Brand Depen Titratabs, generic penicillamine tablets                             |                                    |
| Diagnosis                                                                                     | Severe active rheumatoid arthritis |
| Approval Length                                                                               | 12 month(s)                        |
| Therapy Stage                                                                                 | Reauthorization                    |
| Guideline Type                                                                                | Prior Authorization                |
| <b>Approval Criteria</b><br><b>1 - Documentation of positive clinical response to therapy</b> |                                    |

|                                                                                                                                                                                                     |                              |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|
| Product Name:Brand Depen Titratabs, generic penicillamine tablets                                                                                                                                   |                              |
| Diagnosis                                                                                                                                                                                           | Wilson's disease, Cystinuria |
| Approval Length                                                                                                                                                                                     | 12 month(s)                  |
| Guideline Type                                                                                                                                                                                      | Prior Authorization          |
| <b>Approval Criteria</b><br><b>1 - ONE of the following diagnoses:</b> <ul style="list-style-type: none"> <li>Wilson's disease (i.e., hepatolenticular degeneration)</li> <li>Cystinuria</li> </ul> |                              |

|                                                              |                  |
|--------------------------------------------------------------|------------------|
| Product Name:Brand Cuprimine, generic penicillamine capsules |                  |
| Diagnosis                                                    | Wilson's disease |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                       |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of Wilson's disease (i.e., hepatolenticular degeneration)</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - ONE of the following:</p> <p><b>2.1</b> Failure to BOTH of the following as confirmed by claims history or submission of medical records:</p> <ul style="list-style-type: none"> <li>• penicillamine tablets (generic Depen Titratabs)</li> <li>• trientine 250 mg capsules (generic Syprine)</li> </ul> <p style="text-align: center;"><b>OR</b></p> <p><b>2.2</b> History of intolerance to BOTH of the following (please specify intolerance):</p> <ul style="list-style-type: none"> <li>• penicillamine tablets (generic Depen Titratabs)</li> <li>• trientine 250 mg capsules (generic Syprine)</li> </ul> |                       |

|                                                                            |                                                |
|----------------------------------------------------------------------------|------------------------------------------------|
| Product Name: Brand Cuprimine, generic penicillamine capsules              |                                                |
| Diagnosis                                                                  | Cystinuria, Severe active rheumatoid arthritis |
| Approval Length                                                            | 12 month(s)                                    |
| Therapy Stage                                                              | Initial Authorization                          |
| Guideline Type                                                             | Prior Authorization                            |
| <p><b>Approval Criteria</b></p> <p>1 - ONE of the following diagnoses:</p> |                                                |

- Cystinuria
- Severe active rheumatoid arthritis

**AND**

**2** - ONE of the following:

**2.1** Failure to penicillamine tablets (generic Depen Titratabs) as confirmed by claims history or submission of medical records

**OR**

**2.2** History of intolerance to penicillamine tablets (generic Depen Titratabs) (please specify intolerance)

|                                                                                                   |                                                                  |
|---------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| Product Name: Brand Cuprimine, generic penicillamine capsules                                     |                                                                  |
| Diagnosis                                                                                         | Wilson's disease, Cystinuria, Severe active rheumatoid arthritis |
| Approval Length                                                                                   | 12 month(s)                                                      |
| Therapy Stage                                                                                     | Reauthorization                                                  |
| Guideline Type                                                                                    | Prior Authorization                                              |
| <b>Approval Criteria</b><br><br><b>1</b> - Documentation of positive clinical response to therapy |                                                                  |

|                                                                    |                       |
|--------------------------------------------------------------------|-----------------------|
| Product Name: Brand Syprine, generic trientine hcl 250 mg capsules |                       |
| Diagnosis                                                          | Wilson's disease      |
| Approval Length                                                    | 12 month(s)           |
| Therapy Stage                                                      | Initial Authorization |
| Guideline Type                                                     | Prior Authorization   |
|                                                                    |                       |

**Approval Criteria**

1 - Diagnosis of Wilson's disease (i.e., hepatolenticular degeneration)

Product Name: Brand Syprine, generic trientine hcl 250 mg capsules

|           |                  |
|-----------|------------------|
| Diagnosis | Wilson's disease |
|-----------|------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                 |
|---------------|-----------------|
| Therapy Stage | Reauthorization |
|---------------|-----------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

1 - Documentation of positive clinical response to therapy

Product Name: trientine hcl 500 mg capsules

|           |                  |
|-----------|------------------|
| Diagnosis | Wilson's disease |
|-----------|------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

1 - Diagnosis of Wilson's disease (i.e., hepatolenticular degeneration)

**AND**

2 - ONE of the following:

2.1 Failure to BOTH of the following as confirmed by claims history or submission of medical records:

- penicillamine tablets (generic Depen Titratabs)
- trientine 250 mg capsules (generic Syprine)

**OR**

**2.2** History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- penicillamine tablets (generic Depen Titratabs)
- trientine 250 mg capsules (generic Syprine)

|                                                                                                   |                     |
|---------------------------------------------------------------------------------------------------|---------------------|
| Product Name:trientine hcl 500 mg capsules                                                        |                     |
| Diagnosis                                                                                         | Wilson's disease    |
| Approval Length                                                                                   | 12 month(s)         |
| Therapy Stage                                                                                     | Reauthorization     |
| Guideline Type                                                                                    | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p>1 - Documentation of positive clinical response to therapy</p> |                     |

## 2 . Revision History

| Date     | Notes               |
|----------|---------------------|
| 8/6/2025 | Updated formularies |

Corlanor



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-432257                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Guideline Name</b> | Corlanor                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 12/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                                                  |                                   |
|--------------------------------------------------|-----------------------------------|
| Product Name: Brand Corlanor, generic ivabradine |                                   |
| Diagnosis                                        | Symptomatic Chronic Heart Failure |
| Approval Length                                  | 12 month(s)                       |
| Therapy Stage                                    | Initial Authorization             |
| Guideline Type                                   | Prior Authorization               |

**Approval Criteria**

**1** - ALL of the following:

**1.1** Worsening heart failure in a diagnosis of stable, symptomatic, chronic [e.g., New York Heart Association (NYHA) class II, III, or IV] heart failure

**AND**

**1.2** Patient has a left ventricular ejection fraction (EF) less than or equal to 35%

**AND**

**1.3** The patient is in sinus rhythm

**AND**

**1.4** Patient has a resting heart rate greater than or equal to 70 beats per minute

**AND**

**1.5** ONE of the following:

**1.5.1** Patient is on a stabilized dose and receiving concomitant therapy with maximum tolerated beta blocker (e.g., carvedilol, metoprolol succinate, bisoprolol) as confirmed by claims history or submission of medical records

**OR**

**1.5.2** Patient has a contraindication or intolerance to beta-blocker therapy (please specify contraindication or intolerance)

**AND**



**1.6 ONE of the following:**

**1.6.1** Patient is on a stabilized dose and receiving concomitant therapy with dapagliflozin (Farxiga authorized generic) (includes combination products containing dapagliflozin) as confirmed by claims history or submission of medical records

**OR**

**1.6.2** Patient has a contraindication or intolerance to SGLT2 (sodium-glucose co-transporter 2) inhibitor therapy (please specify contraindication or intolerance)

**AND**

**1.7 ONE of the following:**

**1.7.1** Patient is on a stabilized dose and receiving concomitant therapy with ONE of the following, as confirmed by claims history or submission of medical records:

**1.7.1.1** Angiotensin-converting enzyme (ACE) inhibitor (e.g., captopril, enalapril)

**OR**

**1.7.1.2** Angiotensin II receptor blocker (ARB) (e.g., candesartan, valsartan)

**OR**

**1.7.1.3** Angiotensin receptor-neprilysin inhibitor (ARNI) (e.g., Entresto)

**OR**

**1.7.2** Patient has a contraindication or intolerance to ACE inhibitors, ARBs, and ARNIs (please specify contraindication or intolerance)

**AND**

**1.8 ONE of the following:**

**1.8.1** Patient is on a stabilized dose and receiving concomitant therapy with a maximally tolerated aldosterone antagonist (e.g., eplerenone, spironolactone) as confirmed by claims history or submission of medical records

**OR**

**1.8.2** Patient has a contraindication or intolerance to aldosterone antagonist therapy (please specify contraindication or intolerance)

**AND**

**1.9** Prescribed by or in consultation with a cardiologist

**OR**

**2** - ALL of the following:

**2.1** Diagnosis of stable symptomatic heart failure due to dilated cardiomyopathy (DCM)

**AND**

**2.2** Patient is in sinus rhythm

**AND**

**2.3** Patient has an elevated heart rate

**AND**

**2.4** Prescribed by or in consultation with a cardiologist

**OR**

**3** - Patient is currently established on Corlanor therapy

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                       |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|
| Product Name: Brand Corlanor, generic ivabradine                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                       |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Inappropriate Sinus Tachycardia (IST) |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | 12 month(s)                           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Initial Authorization                 |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Prior Authorization                   |
| <p><b>Approval Criteria</b></p> <p><b>1 - ALL of the following</b></p> <p><b>1.1</b> Diagnosis of inappropriate sinus tachycardia (IST)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>1.2</b> Patient is in sinus rhythm</p> <p style="text-align: center;"><b>AND</b></p> <p><b>1.3</b> ONE of the following:</p> <ul style="list-style-type: none"> <li>• Patient has tried and failed or had an inadequate response to a beta blocker (e.g., carvedilol, metoprolol succinate, bisoprolol) as confirmed by claims history or submission of medical records</li> <li>• Patient has a contraindication or intolerance to beta-blocker therapy (please specify contraindication or intolerance)</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>1.4</b> Prescribed by or in consultation with a cardiologist</p> <p style="text-align: center;"><b>OR</b></p> <p><b>2 - Patient is currently established on Corlanor therapy</b></p> |                                       |

|                                                                                                     |                                                                          |
|-----------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------|
| Product Name: Brand Corlanor, generic ivabradine                                                    |                                                                          |
| Diagnosis                                                                                           | Symptomatic Chronic Heart Failure, Inappropriate Sinus Tachycardia (IST) |
| Approval Length                                                                                     | 12 month(s)                                                              |
| Therapy Stage                                                                                       | Reauthorization                                                          |
| Guideline Type                                                                                      | Prior Authorization                                                      |
| <b>Approval Criteria</b><br><br>1 - Documentation of positive clinical response to Corlanor therapy |                                                                          |

## 2 . Revision History

| Date       | Notes                                                                                                                                      |
|------------|--------------------------------------------------------------------------------------------------------------------------------------------|
| 10/29/2025 | Combined formularies. Updated Farxiga for SGLT2 requirement to reference the preferred authorized generic product. Minor cosmetic updates. |

Cosentyx



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-180202                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Guideline Name</b> | Cosentyx                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 4/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                       |                       |
|-----------------------|-----------------------|
| Product Name:Cosentyx |                       |
| Diagnosis             | Plaque Psoriasis      |
| Approval Length       | 12 month(s)           |
| Therapy Stage         | Initial Authorization |
| Guideline Type        | Prior Authorization   |

## **Approval Criteria**

**1** - Diagnosis of moderate to severe plaque psoriasis

**AND**

**2** - Patient is NOT receiving Cosentyx in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Taltz (ixekizumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

**AND**

**3** - Prescribed by or in consultation with a dermatologist

**AND**

**4** - ONE of the following:

**4.1** Patient is currently on Cosentyx therapy as confirmed by claims history or submission of medical records

**OR**

**4.2** BOTH of the following:

**4.2.1** ONE of the following:

**4.2.1.1** Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of plaque psoriasis as confirmed by claims history or submission of medical records [e.g., Cimzia (certolizumab), adalimumab, Otezla (apremilast), Skyrizi (risankizumab-rzaa), ustekinumab, Tremfya (guselkumab), Enbrel (etanercept)]

**OR**

**4.2.1.2 ALL of the following:**

**4.2.1.2.1** Greater than or equal to 3% body surface area involvement, palmoplantar, facial, or genital involvement, or severe scalp psoriasis

**AND**

**4.2.1.2.2 ONE of the following:**

- Failure of ONE of the following confirmed by claims history or submitted medical records: Corticosteroids (e.g., betamethasone, clobetasol, desonide), Vitamin D analogs (e.g., calcitriol, calcipotriene), Tazarotene, Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus), Anthralin, Coal tar
- History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication): Corticosteroids (e.g., betamethasone, clobetasol, desonide), Vitamin D analogs (e.g., calcitriol, calcipotriene), Tazarotene, Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus), Anthralin, Coal tar

**AND**

**4.2.1.2.3 ONE of the following:**

- Failure of a 3 month trial of methotrexate, at the maximally indicated doses, confirmed by claims history or submitted medical records
- History of intolerance or contraindication to methotrexate (please specify intolerance or contraindication)

**AND**

**4.2.2 ONE of the following:**

**4.2.2.1** Failure to TWO of the following preferred products as confirmed by claims history or submitted medical records:

- One of the preferred adalimumab products\*
- Enbrel (etanercept)
- One of the preferred ustekinumab products\*

**OR**

**4.2.2.2** History of intolerance or contraindication to ALL of the following preferred products (please specify intolerance or contraindication):

- One of the preferred adalimumab products\*
- Enbrel (etanercept)
- One of the preferred ustekinumab products\*

|       |                              |
|-------|------------------------------|
| Notes | *See PDL links in Background |
|-------|------------------------------|

Product Name: Cosentyx

|           |                        |
|-----------|------------------------|
| Diagnosis | Ankylosing Spondylitis |
|-----------|------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

### Approval Criteria

**1** - Diagnosis of active ankylosing spondylitis

**AND**

**2** - Patient is NOT receiving Cosentyx in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

**AND**

**3** - Prescribed by or in consultation with a rheumatologist

**AND**

**4** - ONE of the following:

**4.1** Patient is currently on Cosentyx therapy as confirmed by claims history or submission of medical records



**OR**

**4.2** BOTH of the following:

**4.2.1** ONE of the following:

**4.2.1.1** Failure to TWO NSAIDs (e.g., ibuprofen, naproxen) at maximally indicated doses, each used for at least 4 weeks confirmed by claims history or submitted medical records

**OR**

**4.2.1.2** History of intolerance or contraindication to TWO NSAIDs (please specify intolerance or contraindication)

**OR**

**4.2.1.3** Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of ankylosing spondylitis as confirmed by claims history or submission of medical records [e.g., adalimumab, Simponi (golimumab), Xeljanz/Xeljanz XR (tofacitinib), Rinvoq (upadacitinib), Enbrel (etanercept)]

**AND**

**4.2.2** ONE of the following:

- Failure of BOTH of the following confirmed by claims history or submitted medical records: One of the preferred adalimumab products\*, Enbrel (etanercept)
- History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication): One of the preferred adalimumab products\*, Enbrel (etanercept)

Notes

\*See PDL links in Background

Product Name: Cosentyx

Diagnosis Psoriatic Arthritis (PsA)

Approval Length 12 month(s)

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                       |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1 - Diagnosis of active psoriatic arthritis</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>2 - Patient is NOT receiving Cosentyx in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>3 - Prescribed by or in consultation with a rheumatologist OR dermatologist</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>4 - ONE of the following:</b></p> <p><b>4.1 Patient is currently on Cosentyx therapy as confirmed by claims history or submission of medical records</b></p> <p style="text-align: center;"><b>OR</b></p> <p><b>4.2 BOTH of the following:</b></p> <p><b>4.2.1 ONE of the following:</b></p> <ul style="list-style-type: none"> <li>• Failure of a 3 month trial of methotrexate at the maximally indicated dose confirmed by claims history or submitted medical records</li> <li>• History of intolerance or contraindication to methotrexate (please specify intolerance or contraindication)</li> <li>• Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of psoriatic arthritis as confirmed by claims history or submission of medical records [e.g., Cimzia (certolizumab), adalimumab, Simponi (golimumab),</li> </ul> |                       |

ustekinumab, Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), Otezla (apremilast), Skyrizi (risankizumab-rzaa), Rinvoq (upadacitinib), Enbrel (etanercept)]

**AND**

**4.2.2 ONE of the following:**

**4.2.2.1** Failure to TWO of the following confirmed by claims history or submitted medical records:

- One of the preferred adalimumab products\*
- Enbrel (etanercept)
- One of the preferred ustekinumab products\*

**OR**

**4.2.2.2** History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication):

- One of the preferred adalimumab products\*
- Enbrel (etanercept)
- One of the preferred ustekinumab products\*

Notes

\*See PDL links in Background

Product Name: Cosentyx

|           |                                          |
|-----------|------------------------------------------|
| Diagnosis | Non-radiographic axial spondyloarthritis |
|-----------|------------------------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

1 - Diagnosis of active non-radiographic axial spondyloarthritis

**AND**

**2** - Patient is NOT receiving Cosentyx in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

**AND**

**3** - Prescribed by or in consultation with a rheumatologist

**AND**

**4** - ONE of the following:

**4.1** Patient is currently on Cosentyx therapy as confirmed by claims history or submission of medical records

**OR**

**4.2** ONE of the following:

**4.2.1** Failure to TWO NSAIDs (e.g., ibuprofen, naproxen) at maximally indicated doses, each used for at least 4 weeks confirmed by claims history or submitted medical records

**OR**

**4.2.2** History of intolerance or contraindication to TWO NSAIDs (e.g., ibuprofen, naproxen) (please specify intolerance or contraindication)

**OR**

**4.2.3** Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of non-radiographic axial spondyloarthritis as confirmed by claims history or submission of medical records [e.g., adalimumab, Cimzia (certolizumab), Simponi (golimumab)]

Product Name: Cosentyx

Diagnosis

Enthesitis-Related Arthritis

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                       |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1 - Diagnosis of active enthesitis-related arthritis</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>2 - ONE of the following:</b></p> <p><b>2.1</b> Failure to TWO NSAIDs (e.g., ibuprofen, naproxen) at maximally indicated doses, each used for at least 4 weeks confirmed by claims history or submitted medical records</p> <p style="text-align: center;"><b>OR</b></p> <p><b>2.2</b> History of intolerance or contraindication to TWO NSAIDs (e.g., ibuprofen, naproxen) (please specify intolerance or contraindication)</p> <p style="text-align: center;"><b>OR</b></p> <p><b>2.3</b> Patient is currently on Cosentyx therapy as confirmed by claims history or submission of medical records</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3 - Patient is NOT receiving Cosentyx in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), adalimumab, Cimzia (certolizumab), Simponi (golimumab), Xeljanz (tofacitinib), Rinvoq (upadacitinib)]</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>4 - Prescribed by or in consultation with a rheumatologist</b></p> |                       |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                               |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|
| Product Name: Cosentyx                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                               |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Hidradenitis Suppurativa (HS) |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 12 month(s)                   |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Initial Authorization         |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Prior Authorization           |
| <p><b>Approval Criteria</b></p> <p><b>1 - Diagnosis of moderate to severe hidradenitis suppurativa (i.e., Hurley Stage II or III)</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>2 - ONE of the following:</b></p> <ul style="list-style-type: none"> <li>• Failure to at least ONE oral antibiotic (e.g., doxycycline, clindamycin, rifampin) at maximally indicated doses, as confirmed by claims history or submission of medical records</li> <li>• History of contraindication or intolerance to at least ONE oral antibiotic (e.g., doxycycline, clindamycin, rifampin) (please specify contraindication or intolerance)</li> <li>• Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of hidradenitis suppurativa as confirmed by claims history or submitted medical records [e.g., adalimumab, Bimzelx (bimekizumab-bkzx)].</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>3 - ONE of the following:</b></p> <ul style="list-style-type: none"> <li>• Failure to at least one of the preferred adalimumab products* as confirmed by claims history or submission of medical records</li> <li>• History of contraindication or intolerance to one of the preferred adalimumab products* (please specify contraindication or intolerance)</li> <li>• Patient is currently on Cosentyx therapy as confirmed by claims history or submission of medical records</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>4 - Patient is NOT receiving Cosentyx in combination with another targeted immunomodulator</b></p> |                               |

[e.g., adalimumab, Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

**AND**

**5** - Prescribed by or in consultation with a dermatologist

|       |                              |
|-------|------------------------------|
| Notes | *See PDL links in Background |
|-------|------------------------------|

**Product Name:**Cosentyx

|           |                                                                                                                                                                            |
|-----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Diagnosis | Plaque Psoriasis, Ankylosing Spondylitis, Psoriatic Arthritis (PsA), Non-radiographic Axial Spondyloarthritis, Enthesitis-Related Arthritis, Hidradenitis Suppurativa (HS) |
|-----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                 |
|---------------|-----------------|
| Therapy Stage | Reauthorization |
|---------------|-----------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

## Approval Criteria

**1** - Documentation of positive clinical response to Cosentyx therapy

**AND**

**2** - Patient is NOT receiving Cosentyx in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Taltz (ixekizumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]\*

|       |                                                                                |
|-------|--------------------------------------------------------------------------------|
| Notes | * Examples of drug(s) may not be applicable based on the requested indication. |
|-------|--------------------------------------------------------------------------------|

## 2 . Background

**Benefit/Coverage/Program Information**

**PDL Links:**

CO: <https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html>

HI: <https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html>

MD: <https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-cp-pharmacy.html>

NJ: <https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html>

NM: <https://www.uhcprovider.com/en/health-plans-by-state/new-mexico-health-plans/nm-comm-plan-home/nm-cp-pharmacy.html>

NY: <https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html>

PA: <https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP>

RI: <https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html>

### 3 . Revision History

| Date      | Notes                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|-----------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 2/20/2025 | Updated formularies. Removed reference to brand Stelara. Removed Ilumya step in PsO section – and added preferred ustekinumab as step therapy option in PsO and PsA. Removed requirement that one of the steps in PsO must be adalimumab. Updated step therapy bypass in HS section to bypass oral antibiotic therapy for patients with a history of targeted immunomodulator therapy and bypass for adalimumab section for current utilizers. |



Cotellic



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-163858                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Guideline Name</b> | Cotellic                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 2/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                       |                       |
|-----------------------|-----------------------|
| Product Name:Cotellic |                       |
| Diagnosis             | Melanoma              |
| Approval Length       | 12 month(s)           |
| Therapy Stage         | Initial Authorization |
| Guideline Type        | Prior Authorization   |

**Approval Criteria**

**1** - Diagnosis of melanoma

**AND**

**2** - ONE of the following:

**2.1** Patient has unacceptable toxicities to Tafinlar (dabrafenib)/Mekinist (trametinib) on the basis of agent side-effect profile

**OR**

**2.2** Disease is one of the following:

- Relapsed greater than 3 months after treatment discontinuation
- Unresectable
- Metastatic

**AND**

**3** - Disease is positive for ONE of the following mutations:

- BRAF V600E
- BRAF V600K

**AND**

**4** - Used in combination with Zelboraf (vemurafenib)

|                       |                                      |
|-----------------------|--------------------------------------|
| Product Name:Cotellic |                                      |
| Diagnosis             | Central Nervous System (CNS) Cancers |
| Approval Length       | 12 month(s)                          |
| Therapy Stage         | Initial Authorization                |

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Prior Authorization |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1</b> - One of the following:</p> <ul style="list-style-type: none"> <li>• Circumscribed glioma</li> <li>• Glioblastoma</li> <li>• Limited brain metastases</li> <li>• Extensive brain metastases</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Disease is BRAF V600E positive</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Used in combination with Zelboraf (vemurafenib)</p> |                     |

|                                                                                                                                                                                                                                                   |                                                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|
| Product Name:Cotellic                                                                                                                                                                                                                             |                                                |
| Diagnosis                                                                                                                                                                                                                                         | Melanoma, Central Nervous System (CNS) Cancers |
| Approval Length                                                                                                                                                                                                                                   | 12 month(s)                                    |
| Therapy Stage                                                                                                                                                                                                                                     | Reauthorization                                |
| Guideline Type                                                                                                                                                                                                                                    | Prior Authorization                            |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Patient does not show evidence of progressive disease while on Cotellic therapy</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Used in combination with Zelboraf (vemurafenib)</p> |                                                |

|                                                                                                                                                                                                                          |                       |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Cotellic                                                                                                                                                                                                    |                       |
| Diagnosis                                                                                                                                                                                                                | Histiocytic Neoplasms |
| Approval Length                                                                                                                                                                                                          | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                            | Initial Authorization |
| Guideline Type                                                                                                                                                                                                           | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of one of the following histiocytic neoplasms:</p> <ul style="list-style-type: none"> <li>• Langerhans cell histiocytosis</li> <li>• Erdheim-Chester disease</li> </ul> |                       |

|                                                                                                                            |                       |
|----------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Cotellic                                                                                                      |                       |
| Diagnosis                                                                                                                  | Histiocytic Neoplasms |
| Approval Length                                                                                                            | 12 month(s)           |
| Therapy Stage                                                                                                              | Reauthorization       |
| Guideline Type                                                                                                             | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Patient does not show evidence of progressive disease while on Cotellic therapy</p> |                       |

|                                 |                          |
|---------------------------------|--------------------------|
| Product Name:Cotellic           |                          |
| Diagnosis                       | NCCN Recommended Regimen |
| Approval Length                 | 12 month(s)              |
| Therapy Stage                   | Initial Authorization    |
| Guideline Type                  | Prior Authorization      |
| <p><b>Approval Criteria</b></p> |                          |

**1** - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

| Product Name:Cotellic                                                                                      |                          |
|------------------------------------------------------------------------------------------------------------|--------------------------|
| Diagnosis                                                                                                  | NCCN Recommended Regimen |
| Approval Length                                                                                            | 12 month(s)              |
| Therapy Stage                                                                                              | Reauthorization          |
| Guideline Type                                                                                             | Prior Authorization      |
| <b>Approval Criteria</b><br><br><b>1</b> - Documentation of positive clinical response to Cotellic therapy |                          |

## 2 . Revision History

| Date      | Notes                                                                                |
|-----------|--------------------------------------------------------------------------------------|
| 1/15/2025 | Updated melanoma, central nervous system cancers, and histiocytic neoplasms criteria |

Crenessity



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-363191                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Guideline Name</b> | Crenessity                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Michigan (ACUMI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Pennsylvania (ACUPA)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 9/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                         |
|-------------------------|
| Product Name:Crenessity |
|-------------------------|

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                       |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of classic congenital adrenal hyperplasia (CAH) due to 21-hydroxylase deficiency</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Diagnosis confirmed by one of the following:</p> <ul style="list-style-type: none"> <li>• Pretreatment serum 17-hydroxyprogesterone (17-OHP) level &gt; 3,000 ng/dL</li> <li>• Cosyntropin stimulation 17OHP level &gt; 10,000 ng/dL</li> <li>• Genetic variant in CYP21A2 gene</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Patient is 4 years of age or older</p> <p style="text-align: center;"><b>AND</b></p> <p><b>4</b> - Chronic treatment with a supraphysiologic glucocorticoid (GC) regimen (e.g., dexamethasone, hydrocortisone, methylprednisolone, prednisone, prednisolone) defined as ONE of the following:</p> <p><b>4.1</b> BOTH of the following:</p> <ul style="list-style-type: none"> <li>• Patient is 4 to 17 years old</li> <li>• Daily glucocorticoid dose &gt; 12 mg/m<sup>2</sup> in hydrocortisone dose equivalents</li> </ul> <p style="text-align: center;"><b>OR</b></p> <p><b>4.2</b> BOTH of the following:</p> <ul style="list-style-type: none"> <li>• Patient is at least 18 years old</li> </ul> |                       |

- Daily glucocorticoid dose > 13 mg/m<sup>2</sup>/day in hydrocortisone dose equivalents

**AND**

**5** - Prescribed by an endocrinologist

**AND**

**6** - If the request is for Crenessity oral solution, ONE of the following:

**6.1** Patient is unable to ingest a solid dosage form (e.g., an oral tablet or capsule) due to ONE of the following:

- Age
- Oral-motor difficulties
- Dysphagia

**OR**

**6.2** Patient utilizes a feeding tube for medication administration

|                                                                                                                                                                                                                                                                                                                                                                                                            |                     |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Crenessity                                                                                                                                                                                                                                                                                                                                                                                    |                     |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                            | 12 month(s)         |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                              | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                             | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of positive clinical response to Crenessity therapy (e.g., reduction in total glucocorticoid daily dose, decreased androstenedione levels)</p> <p><b>AND</b></p> <p><b>2</b> - Patient will continue to receive concomitant glucocorticoid replacement (e.g., dexamethasone, hydrocortisone, methylprednisolone, prednisone, prednisolone)</p> |                     |



**AND**

**3** - Prescribed by an endocrinologist

**AND**

**4** - If the request is for Crenessity oral solution, ONE of the following:

**4.1** Patient is unable to ingest a solid dosage form (e.g., an oral tablet or capsule) due to ONE of the following:

- Age
- Oral-motor difficulties
- Dysphagia

**OR**

**4.2** Patient utilizes a feeding tube for medication administration

## 2 . Revision History

| Date      | Notes                         |
|-----------|-------------------------------|
| 8/11/2025 | Updated formularies to add IN |

Ctexli



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-419219                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Guideline Name</b> | Ctexli                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State Michigan (ACUMI)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 11/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                     |                       |
|---------------------|-----------------------|
| Product Name:Ctexli |                       |
| Approval Length     | 12 month(s)           |
| Therapy Stage       | Initial Authorization |

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Prior Authorization |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of cerebrotendinous xanthomatosis (cholestanol storage disease)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Disease is confirmed by the presence of pathogenic variant(s) in the CYP27A1 gene</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Prescribed by or in consultation with ONE of the following:</p> <ul style="list-style-type: none"> <li>• Endocrinologist</li> <li>• Geneticist</li> <li>• Neurologist</li> </ul> |                     |

|                                                                                                                                                                                                                                                                                                                                       |                     |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Ctexli                                                                                                                                                                                                                                                                                                                   |                     |
| Approval Length                                                                                                                                                                                                                                                                                                                       | 12 month(s)         |
| Therapy Stage                                                                                                                                                                                                                                                                                                                         | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                                                                                                        | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of positive clinical response to Ctexli therapy</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Prescribed by or in consultation with ONE of the following:</p> <ul style="list-style-type: none"> <li>• Endocrinologist</li> <li>• Geneticist</li> </ul> |                     |

- Neurologist

## 2 . Revision History

| Date       | Notes                                                                                                                                                                                                   |
|------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 10/15/2025 | Updated formularies to add IN for eff 11/1/25. Updated GPI entry for Ctexli. Removed note regarding approving Ctexli at NDC level in both initial and reauth sections. No changes to clinical criteria. |

Cuvrior



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|-----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-224221                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Guideline Name</b> | Cuvrior                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State Michigan (ACUMI)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 5/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                      |                       |
|----------------------|-----------------------|
| Product Name:Cuvrior |                       |
| Approval Length      | 12 month(s)           |
| Therapy Stage        | Initial Authorization |

| Guideline Type | Prior Authorization                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|----------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                | <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of Wilson's disease</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Patient is de-coppered [i.e., serum non-ceruloplasmin copper (NCC) level greater than or equal to 25 and less than or equal to 150 mcg/L (micrograms/liter)]</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Patient is tolerant to penicillamine</p> <p style="text-align: center;"><b>AND</b></p> <p><b>4</b> - Prescriber provides a reason or special circumstance why the patient cannot use penicillamine tablets (generic Depen Titratabs)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>5</b> - ONE of the following:</p> <p><b>5.1</b> Failure to trientine 250 mg capsules (generic Syprine) as confirmed by claims history or submission of medical records</p> <p style="text-align: center;"><b>OR</b></p> <p><b>5.2</b> History of intolerance to trientine 250 mg capsules (generic Syprine) (please specify intolerance)</p> <p style="text-align: center;"><b>AND</b></p> |

**6** - Prescribed by a hepatologist

|                                                                                                                                                                                                                                                                                                                                                |                     |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Cuvrior                                                                                                                                                                                                                                                                                                                           |                     |
| Approval Length                                                                                                                                                                                                                                                                                                                                | 12 month(s)         |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                  | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                 | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p>1 - Documentation of positive clinical response to Cuvrior therapy (e.g., increased 24-hour urinary copper excretion from baseline, normalization of serum free copper, prevention of or improvement in symptoms)</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Prescribed by a hepatologist</p> |                     |

## 2 . Revision History

| Date      | Notes                                                  |
|-----------|--------------------------------------------------------|
| 3/24/2025 | Combined formularies. No changes to clinical criteria. |

Cystaran, Cystadrops



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-164695                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Guideline Name</b> | Cystaran, Cystadrops                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State Pennsylvania (ACUPA)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 2/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                                   |            |
|-----------------------------------|------------|
| Product Name:Cystaran, Cystadrops |            |
| Diagnosis                         | Cystinosis |



|                                                             |                     |
|-------------------------------------------------------------|---------------------|
| Approval Length                                             | 12 month(s)         |
| Guideline Type                                              | Prior Authorization |
| <b>Approval Criteria</b><br><br>1 - Diagnosis of cystinosis |                     |

## 2 . Revision History

| Date     | Notes                                                                       |
|----------|-----------------------------------------------------------------------------|
| 2/4/2025 | Adding Indiana and PA Medicaid formularies. No change to clinical criteria. |

Daliresp



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-165155                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Guideline Name</b> | Daliresp                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 4/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                                                   |                     |
|---------------------------------------------------|---------------------|
| Product Name: Brand Daliresp, generic roflumilast |                     |
| Approval Length                                   | 12 month(s)         |
| Guideline Type                                    | Prior Authorization |
| Approval Criteria                                 |                     |

1 - Diagnosis of chronic obstructive pulmonary disease (COPD)

## 2 . Revision History

| Date      | Notes                                                            |
|-----------|------------------------------------------------------------------|
| 2/13/2025 | Updated formularies. Removed all criteria except diagnosis check |

Danziten



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-173219                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Guideline Name</b> | Danziten                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 4/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                       |                          |
|-----------------------|--------------------------|
| Product Name:Danziten |                          |
| Diagnosis             | Chronic Myeloid Leukemia |
| Approval Length       | 12 month(s)              |
| Therapy Stage         | Initial Authorization    |

|                                                                              |                     |
|------------------------------------------------------------------------------|---------------------|
| Guideline Type                                                               | Prior Authorization |
| <b>Approval Criteria</b><br><b>1</b> - Diagnosis of chronic myeloid leukemia |                     |

|                                                                                                                                      |                                         |
|--------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|
| Product Name:Danziten                                                                                                                |                                         |
| Diagnosis                                                                                                                            | Acute Lymphoblastic Leukemia (Ph+B-ALL) |
| Approval Length                                                                                                                      | 12 month(s)                             |
| Therapy Stage                                                                                                                        | Initial Authorization                   |
| Guideline Type                                                                                                                       | Prior Authorization                     |
| <b>Approval Criteria</b><br><b>1</b> - Diagnosis of Philadelphia chromosome-positive B-cell acute lymphoblastic leukemia (Ph+ B-ALL) |                                         |

|                                                                                                                    |                       |
|--------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Danziten                                                                                              |                       |
| Diagnosis                                                                                                          | Soft Tissue Sarcoma   |
| Approval Length                                                                                                    | 12 month(s)           |
| Therapy Stage                                                                                                      | Initial Authorization |
| Guideline Type                                                                                                     | Prior Authorization   |
| <b>Approval Criteria</b><br><b>1</b> - Diagnosis of pigmented villonodular synovitis/tenosynovial giant cell tumor |                       |

|                       |                                                                                        |
|-----------------------|----------------------------------------------------------------------------------------|
| Product Name:Danziten |                                                                                        |
| Diagnosis             | Chronic Myeloid Leukemia, Acute Lymphoblastic Leukemia (Ph+B-ALL), Soft Tissue Sarcoma |
| Approval Length       | 12 month(s)                                                                            |

|                                                                                                                 |                     |
|-----------------------------------------------------------------------------------------------------------------|---------------------|
| Therapy Stage                                                                                                   | Reauthorization     |
| Guideline Type                                                                                                  | Prior Authorization |
| <b>Approval Criteria</b><br>1 - Patient does not show evidence of progressive disease while on Danziten therapy |                     |

|                                                                                                                                     |                           |
|-------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Danziten                                                                                                               |                           |
| Diagnosis                                                                                                                           | NCCN Recommended Regimens |
| Approval Length                                                                                                                     | 12 month(s)               |
| Therapy Stage                                                                                                                       | Initial Authorization     |
| Guideline Type                                                                                                                      | Prior Authorization       |
| <b>Approval Criteria</b><br>1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium |                           |

|                                                                                                 |                           |
|-------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Danziten                                                                           |                           |
| Diagnosis                                                                                       | NCCN Recommended Regimens |
| Approval Length                                                                                 | 12 month(s)               |
| Therapy Stage                                                                                   | Reauthorization           |
| Guideline Type                                                                                  | Prior Authorization       |
| <b>Approval Criteria</b><br>1 - Documentation of positive clinical response to Danziten therapy |                           |

## 2 . Revision History

UnitedHealthcare Community Plan of New Jersey – Clinical Pharmacy Guidelines

| Date      | Notes       |
|-----------|-------------|
| 2/18/2025 | New program |

Daraprim



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-315214                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Guideline Name</b> | Daraprim                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Pennsylvania (ACUPA)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 8/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                                                                                                                         |                     |
|-------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name: Brand Daraprim, generic pyrimethamine                                                                     |                     |
| Approval Length                                                                                                         | 12 month(s)         |
| Guideline Type                                                                                                          | Prior Authorization |
| <b>Approval Criteria</b><br><br>1 - Submission of medical records (e.g., chart notes) documenting ONE of the following: |                     |



**1.1 Treatment of severe acquired toxoplasmosis, including toxoplasmic encephalitis**

**OR**

**1.2 Treatment of congenital toxoplasmosis**

**OR**

**1.3 Secondary prophylaxis of toxoplasmic encephalitis**

**OR**

**1.4 ALL of the following:**

**1.4.1** Primary pneumocystis pneumonia (PCP) prophylaxis in human immunodeficiency virus (HIV)-infected patients or as secondary prophylaxis in HIV-infected patients who have been treated for an acute episode of pneumocystis pneumonia

**AND**

**1.4.2** Patient has experienced intolerance to prior prophylaxis with trimethoprim-sulfamethoxazole (TMP-SMX)

**AND**

**1.4.3 One of the following:**

- Patient has been re-challenged with trimethoprim-sulfamethoxazole (TMP-SMX) using a desensitization protocol and is still unable to tolerate
- Evidence of moderately severe or life threatening-reaction to trimethoprim-sulfamethoxazole (TMP-SMX) in the past [e.g., toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome]

**OR**

**1.5 ALL of the following:**

**1.5.1** Primary prophylaxis of toxoplasmic encephalitis

**AND**

**1.5.2** Toxoplasma immunoglobulin G (IgG) positive

**AND**

**1.5.3** CD4 count less than or equal to 100 cells per mm<sup>3</sup> if initiating prophylaxis or CD4 count 100-200 cells per mm<sup>3</sup> if reinstituting prophylaxis\*

**AND**

**1.5.4** Will be used in combination with dapsone or atovaquone

**AND**

**1.5.5** Patient has experienced intolerance to prior prophylaxis with trimethoprim-sulfamethoxazole (TMP-SMX)

**AND**

**1.5.6** ONE of the following:

- Patient has been re-challenged with trimethoprim-sulfamethoxazole (TMP-SMX) using a desensitization protocol and is still unable to tolerate
- Evidence of moderately severe or life threatening-reaction to trimethoprim-sulfamethoxazole (TMP-SMX) in the past [e.g., toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome]

Notes

\*Consider discontinuation of primary prophylaxis if CD4 count > 200 cells/mm<sup>3</sup> for > 3 months after institution of combination antiretroviral therapy.

Product Name: Brand Daraprim\*, generic pyrimethamine\*

|                                                                                                                                                                                                                       |                                                                                                                                            |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------|
| Guideline Type                                                                                                                                                                                                        | Reject 88 - Therapeutic Duplication                                                                                                        |
| <b>Approval Criteria</b><br><br><b>1</b> - There is a reason or special circumstances why the patient must be on Daraprim (pyrimethamine) commercial tablets and a compound containing pyrimethamine at the same time |                                                                                                                                            |
| Notes                                                                                                                                                                                                                 | *Approval Length: 2 months (if deemed medically necessary for long-term use by the prescriber, authorization will be issued for 12 months) |

## 2 . Revision History

| Date     | Notes                                                              |
|----------|--------------------------------------------------------------------|
| 7/4/2025 | Updated formularies. Minor language updates and formatting changes |

Daurismo



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-181191                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Guideline Name</b> | Daurismo                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 4/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                       |                        |
|-----------------------|------------------------|
| Product Name:Daurismo |                        |
| Diagnosis             | Acute Myeloid Leukemia |
| Approval Length       | 12 month(s)            |
| Therapy Stage         | Initial Authorization  |

| Guideline Type | Prior Authorization                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                | <p><b>Approval Criteria</b></p> <p><b>1 - ONE of the following:</b></p> <p><b>1.1</b> Diagnosis of newly-diagnosed acute myeloid leukemia (AML)</p> <p style="text-align: center;"><b>OR</b></p> <p><b>1.2</b> Relapsed/refractory disease with ALL of the following:</p> <p><b>1.2.1</b> Given as a component of repeating the initial successful induction regimen</p> <p style="text-align: center;"><b>AND</b></p> <p><b>1.2.2</b> Late relapse (greater than or equal to 12 months since induction regimen)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>1.2.3</b> Initial therapy was not administered continuously</p> <p style="text-align: center;"><b>AND</b></p> <p><b>1.2.4</b> Initial therapy was not stopped due to development of clinical resistance</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2 - Daurismo therapy to be given in combination with low-dose cytarabine</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>3 - ONE of the following:</b></p> |

**3.1** Patient is at least 75 years old

**OR**

**3.2** Patient has significant comorbidities that preclude the use of intensive induction chemotherapy [e.g., severe cardiac disease, Eastern Cooperative Oncology Group (ECOG) performance status greater than or equal to 2, baseline creatinine greater than 1.3 milligrams/deciliter]

**Product Name:**Daurismo

|           |                        |
|-----------|------------------------|
| Diagnosis | Acute Myeloid Leukemia |
|-----------|------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                 |
|---------------|-----------------|
| Therapy Stage | Reauthorization |
|---------------|-----------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

**1** - Patient does not show evidence of progressive disease while on Daurismo therapy

**Product Name:**Daurismo

|           |                           |
|-----------|---------------------------|
| Diagnosis | NCCN Recommended Regimens |
|-----------|---------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

**1** - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

**Product Name:**Daurismo

|           |                           |
|-----------|---------------------------|
| Diagnosis | NCCN Recommended Regimens |
|-----------|---------------------------|

|                                                                                                     |                     |
|-----------------------------------------------------------------------------------------------------|---------------------|
| Approval Length                                                                                     | 12 month(s)         |
| Therapy Stage                                                                                       | Reauthorization     |
| Guideline Type                                                                                      | Prior Authorization |
| <b>Approval Criteria</b><br><br>1 - Documentation of positive clinical response to Daurismo therapy |                     |

## 2 . Revision History

| Date      | Notes                                                  |
|-----------|--------------------------------------------------------|
| 2/20/2025 | Combined formularies. No changes to clinical criteria. |

Daybue



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-150910                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Guideline Name</b> | Daybue                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 8/3/2024 |
|-----------------|----------|

## 1 . Criteria

|                     |                       |
|---------------------|-----------------------|
| Product Name:Daybue |                       |
| Approval Length     | 12 month(s)           |
| Therapy Stage       | Initial Authorization |
| Guideline Type      | Prior Authorization   |
|                     |                       |



### Approval Criteria

**1** - Diagnosis of Rett Syndrome (RTT) confirmed by ONE of the following:

**1.1** ALL of the following clinical signs and symptoms:

- A pattern of development, regression, then recovery or stabilization
- Partial or complete loss of purposeful hand skills such as grasping with fingers, reaching for things, or touching things on purpose
- Partial or complete loss of spoken language
- Repetitive hand movements, such as wringing the hands, washing, squeezing, clapping, or rubbing
- Gait abnormalities, including walking on toes or with an unsteady, wide-based, stiff-legged gait

**OR**

**1.2** Confirmed genetic mutation in the MECP2 gene

**AND**

**2** - Prescribed by, or in consultation with, ONE of the following:

- Geneticist
- Pediatrician who specializes in childhood neurological or developmental disorders
- Neurologist

|                                                                                                      |                     |
|------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Daybue                                                                                  |                     |
| Approval Length                                                                                      | 12 month(s)         |
| Therapy Stage                                                                                        | Reauthorization     |
| Guideline Type                                                                                       | Prior Authorization |
| <b>Approval Criteria</b><br><b>1</b> - Documentation of positive clinical response to Daybue therapy |                     |

## 2 . Revision History

| Date     | Notes                                                         |
|----------|---------------------------------------------------------------|
| 8/2/2024 | Updated initial approval duration from 6 months to 12 months. |

DEKAs Plus



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-135059                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Guideline Name</b> | DEKAs Plus                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>•</li> <li>•</li> <li>•</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 1/1/2024 |
|-----------------|----------|

## 1 . Criteria

|                                           |                     |
|-------------------------------------------|---------------------|
| Product Name:DEKAs Plus Ocean, DEKAs Plus |                     |
| Diagnosis                                 | Cystic Fibrosis     |
| Approval Length                           | 12 month(s)         |
| Guideline Type                            | Prior Authorization |

**Approval Criteria**

1 - Diagnosis of cystic fibrosis

**2 . Revision History**

| Date       | Notes                                 |
|------------|---------------------------------------|
| 10/16/2023 | Updated formularies, cleaned up GPIs. |

Difcid



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-389199                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Guideline Name</b> | Difcid                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 10/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                                                 |                     |
|-------------------------------------------------|---------------------|
| Product Name: Brand Difcid, generic fidaxomicin |                     |
| Approval Length                                 | 1 month(s)          |
| Guideline Type                                  | Prior Authorization |
| Approval Criteria                               |                     |

**1 - Diagnosis of Clostridioides difficile-associated diarrhea (CDAD) [previously known as Clostridium difficile-associated diarrhea]**

**AND**

**2 - ONE of the following:**

**2.1 Failure to one of the following confirmed by claims history or submitted medical records:**

- Firvanq (vancomycin) oral solution
- vancomycin 125 mg or 250 mg capsules
- vancomycin 25 mg/ml or 50 mg/ml oral solution

**OR**

**2.2 History of intolerance or contraindication to all of the following: (please specify intolerance or contraindication)**

- Firvanq (vancomycin) oral solution
- vancomycin 125 mg or 250 mg capsules
- vancomycin 25 mg/ml or 50 mg/ml oral solution

**OR**

**2.3 For continuation of prior Difcid therapy**

## 2 . Revision History

| Date     | Notes                                                                                                |
|----------|------------------------------------------------------------------------------------------------------|
| 9/8/2025 | Updated formularies. Added generic. Added "confirmed by claims history or submitted medical records" |

Dojolvi



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-322187                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Guideline Name</b> | Dojolvi                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Michigan (ACUMI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Pennsylvania (ACUPA)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 8/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                      |
|----------------------|
| Product Name:Dojolvi |
|----------------------|

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                       |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Submission of medical records confirming the diagnosis of long-chain fatty acid oxidation disorders (LC-FAOD) with at least two of the following diagnostic criteria:</p> <ul style="list-style-type: none"> <li>• Disease specific elevation of acyl-carnitines on a newborn blood spot or in plasma</li> <li>• Low enzyme activity in cultured fibroblasts</li> <li>• Genetic testing demonstrating one or more pathogenic mutations in a gene associated with long-chain fatty acid oxidation disorders (e.g., CPT2, ACADVL, HADHA, or HADHB)</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Patient is not receiving Dojolvi in combination with any other medium-chain triglyceride (MCT) products</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Prescribed by a board-certified medical geneticist experienced in the treatment of long-chain fatty acid oxidation disorders (LC-FAOD)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>4</b> - Target recommended daily dosage does not exceed 35% of the patient's total prescribed daily caloric intake (DCI)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>5</b> - Patient is receiving disease related dietary management</p> <p style="text-align: center;"><b>AND</b></p> |                       |



**6** - If not diagnosed by newborn screening, patient has a history of clinical manifestations of long-chain fatty acid oxidation disorders LC-FAOD (e.g., rhabdomyolysis)

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                     |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Dojolvi                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                     |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 12 month(s)         |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of positive clinical response to Dojolvi therapy (e.g., increased cardiac efficiency, decreased left ventricular wall mass, decreased incidence of rhabdomyolysis, etc.)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Patient is not receiving Dojolvi in combination with any other medium-chain triglyceride (MCT) product</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Prescribed by a board-certified medical geneticist experienced in the treatment of long-chain fatty acid oxidation disorders (LC-FAOD)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>4</b> - Target recommended daily dosage does not exceed 35% of the patient's total prescribed daily caloric intake (DCI)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>5</b> - Patient is receiving disease related dietary management</p> |                     |

## 2 . Revision History

| Date     | Notes               |
|----------|---------------------|
| 7/7/2025 | Updated formularies |

Doptelet



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-428194                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Guideline Name</b> | Doptelet                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 12/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                       |                                                                                                  |
|-----------------------|--------------------------------------------------------------------------------------------------|
| Product Name:Doptelet |                                                                                                  |
| Diagnosis             | Thrombocytopenia in patients with chronic liver disease who are scheduled to undergo a procedure |
| Approval Length       | 1 month(s)                                                                                       |

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Prior Authorization |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of thrombocytopenia</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Patient has chronic liver disease</p> <p style="text-align: center;"><b>AND</b></p> <p>3 - Patient is scheduled to undergo a procedure</p> <p style="text-align: center;"><b>AND</b></p> <p>4 - ONE of the following:</p> <ul style="list-style-type: none"> <li>• Failure to Mulpleta (lusutrombopag) as confirmed by claims history or submission of medical records</li> <li>• History of contraindication or intolerance to Mulpleta (lusutrombopag) (please specify contraindication or intolerance)</li> </ul> |                     |

|                                                                                               |                                       |
|-----------------------------------------------------------------------------------------------|---------------------------------------|
| Product Name:Doptelet                                                                         |                                       |
| Diagnosis                                                                                     | Chronic Immune Thrombocytopenia (ITP) |
| Approval Length                                                                               | 12 month(s)                           |
| Therapy Stage                                                                                 | Initial Authorization                 |
| Guideline Type                                                                                | Prior Authorization                   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of chronic immune thrombocytopenia (ITP)</p> |                                       |

**AND**

**2 - ONE of the following:**

**2.1 BOTH of the following:**

**2.1.1 ONE of the following:**

**2.1.1.1** Failure to at least ONE of the following as confirmed by claims history or submission of medical records:

- Corticosteroids
- Immunoglobulins

**OR**

**2.1.1.2** History of contraindication or intolerance to BOTH of the following (please specify contraindication or intolerance):

- Corticosteroids
- Immunoglobulins

**AND**

**2.1.2 ONE of the following:**

- Failure to eltrombopag olamine (generic Promacta) as confirmed by claims history or submission of medical records
- History of contraindication or intolerance to eltrombopag olamine (generic Promacta) (please specify contraindication or intolerance)

**OR**

**2.2** Patient is currently on Doptelet therapy

Product Name:Doptelet

Diagnosis

Chronic Immune Thrombocytopenia (ITP)

|                                                                                                     |                     |
|-----------------------------------------------------------------------------------------------------|---------------------|
| Approval Length                                                                                     | 12 month(s)         |
| Therapy Stage                                                                                       | Reauthorization     |
| Guideline Type                                                                                      | Prior Authorization |
| <b>Approval Criteria</b><br><br>1 - Documentation of positive clinical response to Doptelet therapy |                     |

## 2 . Revision History

| Date       | Notes                                                                                                |
|------------|------------------------------------------------------------------------------------------------------|
| 10/24/2025 | Updated formularies to remove IN for eff 12/1/25. Updated GPI list. No changes to clinical criteria. |

## DPP-4 Inhibitors



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-233453                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Guideline Name</b> | DPP-4 Inhibitors                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 6/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                                                                                                            |                     |
|------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Alogliptin, Alogliptin/metformin, Alogliptin/pioglitazone, Brand Onglyza, generic saxagliptin |                     |
| Approval Length                                                                                            | 12 month(s)         |
| Guideline Type                                                                                             | Prior Authorization |
| <b>Approval Criteria</b>                                                                                   |                     |

**1** - Submission of medical records (e.g., chart notes) confirming diagnosis of type 2 diabetes mellitus as evidenced by one of the following laboratory values:

- A1C greater than or equal to 6.5%
- Fasting plasma glucose (FPG) greater than or equal to 126 mg/dL
- 2-hour plasma glucose (PG) greater than or equal to 200 mg/dL during oral glucose tolerance test
- Random plasma glucose greater than or equal to 200 mg/dL in patient with classic symptoms of hyperglycemia or hyperglycemic crisis

**OR**

**2** - For patients requiring ongoing treatment for type 2 diabetes mellitus (i.e., diagnosed greater than 2 years ago), submission of medical records (e.g., chart notes) confirming diagnosis of type 2 diabetes mellitus

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                       |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Nesina, Kazano, Oseni                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                       |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - ONE of the following:</p> <p><b>1.1</b> Submission of medical records (e.g., chart notes) confirming diagnosis of type 2 diabetes mellitus as evidenced by one of the following laboratory values:</p> <ul style="list-style-type: none"> <li>• A1C greater than or equal to 6.5%</li> <li>• Fasting plasma glucose (FPG) greater than or equal to 126 mg/dL</li> <li>• 2-hour plasma glucose (PG) greater than or equal to 200 mg/dL during oral glucose tolerance test</li> <li>• Random plasma glucose greater than or equal to 200 mg/dL in patient with classic symptoms of hyperglycemia or hyperglycemic crisis</li> </ul> <p style="text-align: center;"><b>OR</b></p> <p><b>1.2</b> For patients requiring ongoing treatment for type 2 diabetes mellitus (i.e., diagnosed</p> |                       |



greater than 2 years ago), submission of medical records (e.g., chart notes) confirming diagnosis of type 2 diabetes mellitus

**AND**

**2** - The prescriber has given a clinical reason or special circumstance why the patient is unable to use ONE of the following (please document reason/special circumstance):

- Alogliptin (authorized generic of Nesina)
- Alogliptin/metformin (authorized generic of Kazano)
- Alogliptin/pioglitazone (authorized generic of Oseni)

Product Name:Nesina, Kazano, Oseni

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                 |
|---------------|-----------------|
| Therapy Stage | Reauthorization |
|---------------|-----------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

### Approval Criteria

**1** - Documentation of positive clinical response to therapy (e.g., improved A1C)

**AND**

**2** - The prescriber has given a clinical reason or special circumstance why the patient is unable to use ONE of the following (please document reason/special circumstance):

- Alogliptin (authorized generic of Nesina)
- Alogliptin/metformin (authorized generic of Kazano)
- Alogliptin/pioglitazone (authorized generic of Oseni)

Product Name:Brynovin, Januvia, Janumet, Janumet XR, Brand Kombiglyze XR, generic saxagliptin/metformin ER, Tradjenta, Jentadueto, Jentadueto XR, Zituvimet, Zituvimet XR, Zituvio, Sitagliptin, Sitagliptin/metformin

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Prior Authorization |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1 - ONE of the following:</b></p> <p><b>1.1</b> Submission of medical records (e.g., chart notes) confirming diagnosis of type 2 diabetes mellitus as evidenced by ONE of the following laboratory values:</p> <ul style="list-style-type: none"> <li>• A1C greater than or equal to 6.5%</li> <li>• Fasting plasma glucose (FPG) greater than or equal to 126 mg/dL</li> <li>• 2-hour plasma glucose (PG) greater than or equal to 200 mg/dL during oral glucose tolerance test</li> <li>• Random plasma glucose greater than or equal to 200 mg/dL in patient with classic symptoms of hyperglycemia or hyperglycemic crisis</li> </ul> <p style="text-align: center;"><b>OR</b></p> <p><b>1.2</b> For patients requiring ongoing treatment for type 2 diabetes mellitus (i.e., diagnosed greater than 2 years ago), submission of medical records (e.g., chart notes) confirming diagnosis of type 2 diabetes mellitus</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2 - ONE of the following:</b></p> <p><b>2.1</b> Failure to a 90 day trial with ONE of the following as confirmed by claims history or submission of medical records:</p> <ul style="list-style-type: none"> <li>• Alogliptin (authorized generic of Nesina)</li> <li>• Alogliptin/metformin (authorized generic of Kazano)</li> <li>• Alogliptin/pioglitazone (authorized generic of Oseni)</li> <li>• Saxagliptin (generic Onglyza)</li> </ul> <p style="text-align: center;"><b>OR</b></p> <p><b>2.2</b> History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication)</p> <ul style="list-style-type: none"> <li>• Alogliptin (authorized generic of Nesina)</li> </ul> |                     |

- Alogliptin/metformin (authorized generic of Kazano)
- Alogliptin/pioglitazone (authorized generic of Oseni)
- Saxagliptin (generic Onglyza)

Product Name: Brynovin, Januvia, Janumet, Janumet XR, Brand Kombiglyze XR, generic saxagliptin/metformin ER, Tradjenta, Jentadueto, Jentadueto XR, Zituvimet, Zituvimet XR, Zituvio, Sitagliptin, Sitagliptin/metformin

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                 |
|---------------|-----------------|
| Therapy Stage | Reauthorization |
|---------------|-----------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

### Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., improved A1C)

## 2 . Revision History

| Date     | Notes          |
|----------|----------------|
| 4/4/2025 | Added Brynovin |

Dry Eye Disease



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-450189                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Guideline Name</b> | Dry Eye Disease                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 12/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                                                                                                 |                       |
|-------------------------------------------------------------------------------------------------|-----------------------|
| Product Name: Cequa, Miebo, Brand Restasis, Restasis Multidose, Tryptyr, Tyrvaya, Vevye, Xiidra |                       |
| Approval Length                                                                                 | 12 month(s)           |
| Therapy Stage                                                                                   | Initial Authorization |
| Guideline Type                                                                                  | Prior Authorization   |

### **Approval Criteria**

**1** - Diagnosis of ONE of the following:

- Moderate to severe keratoconjunctivitis sicca
- Moderate to severe dry eye disease

**AND**

**2** - NOT prescribed to manage dry eyes peri-operative elective eye surgery [e.g., LASIK (laser-assisted in situ keratomileusis)]

**AND**

**3** - Failure to at least one OTC (over-the-counter) artificial tear product (e.g., Systane Ultra, Akwa Tears, Refresh Optive, Soothe XP) as confirmed by claims history or submission of medical records

**AND**

**4** - ONE of the following:

**4.1** Failure to cyclosporine emulsion 0.05% (generic Restasis) as confirmed by claims history or submission of medical records

**OR**

**4.2** History of contraindication or intolerance to cyclosporine emulsion 0.05% (generic Restasis) (please specify contraindication or intolerance)

**AND**

**5** - Medication will NOT be used in combination with another prescription product for dry eye disease or keratoconjunctivitis sicca (e.g., Miebo, Restasis single dose-vials, Tyrvaya, Xiidra)

**AND**

**6** - Prescribed by or in consultation with ONE of the following:

- Ophthalmologist
- Optometrist
- Rheumatologist

Product Name:generic cyclosporine 0.05% emulsion

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

### Approval Criteria

**1** - Diagnosis of ONE of the following:

- Moderate to severe keratoconjunctivitis sicca
- Moderate to severe dry eye disease

**AND**

**2** - NOT prescribed to manage dry eyes peri-operative elective eye surgery [e.g., LASIK (laser-assisted in situ keratomileusis)]

**AND**

**3** - Failure to at least one OTC (over-the-counter) artificial tear product (e.g., Systane Ultra, Akwa Tears, Refresh Optive, Soothe XP) as confirmed by claims history or submission of medical records

**AND**

**4** - Medication will NOT be used in combination with another prescription product for dry eye disease or keratoconjunctivitis sicca (e.g., Miebo, Restasis single dose-vials, Tyrvaya, Xiidra)

**AND**

**5** - Prescribed by or in consultation with ONE of the following:

- Ophthalmologist
- Optometrist
- Rheumatologist

Product Name: Cequa, Miebo, Brand Restasis, generic cyclosporine 0.05% emulsion, Restasis Multidose, Tyrvaya, Vevye, Xiidra, Tryptyr

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                 |
|---------------|-----------------|
| Therapy Stage | Reauthorization |
|---------------|-----------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

### Approval Criteria

**1** - Patient has demonstrated clinically significant improvement with therapy

**AND**

**2** - Medication will NOT be used in combination with another prescription product for dry eye disease or keratoconjunctivitis sicca (e.g., Miebo, Restasis single dose-vials, Tyrvaya, Xiidra)

## 2 . Revision History

| Date       | Notes           |
|------------|-----------------|
| 11/10/2025 | Added Tryptyr . |

Duexis and Vimovo



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-315212                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Guideline Name</b> | Duexis and Vimovo                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 8/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                                                         |                     |
|---------------------------------------------------------|---------------------|
| Product Name:Brand Duexis, generic ibuprofen/famotidine |                     |
| Approval Length                                         | 12 month(s)         |
| Guideline Type                                          | Prior Authorization |
| Approval Criteria                                       |                     |



**1 - ONE** of the following risk factors for NSAID (non-steroidal anti-inflammatory drug)-induced adverse GI (gastrointestinal) events:

- Patient is greater than or equal to 65 years of age
- Prior history of peptic, gastric, or duodenal ulcer
- History of NSAID-related ulcer
- History of clinically significant GI bleeding
- Untreated or active H. Pylori (Helicobacter pylori) gastritis
- Concurrent use of oral corticosteroids (e.g., prednisone, prednisolone, dexamethasone)
- Concurrent use of anticoagulants (e.g., warfarin, heparin)
- Concurrent use of antiplatelets (e.g., aspirin including low-dose, clopidogrel)

**AND**

**2 - ONE** of the following:

**2.1** Failure to THREE combinations of preferred\* NSAIDs, one of which must be celecoxib (generic Celebrex), taken concomitantly with preferred\* H2-receptor antagonists, as confirmed by claims history or submitted medical records

**OR**

**2.2** History of contraindication or intolerance to ALL preferred\* NSAIDs and ALL preferred\* H2-receptor antagonists (please specify contraindication or intolerance)

**AND**

**3 - Physician** has provided rationale for needing to use fixed-dose combination therapy with Duexis instead of taking individual products in combination

|       |                           |
|-------|---------------------------|
| Notes | *PDL links in Background. |
|-------|---------------------------|

|                                                           |                     |
|-----------------------------------------------------------|---------------------|
| Product Name: Brand Vimovo, generic naproxen/esomeprazole |                     |
| Approval Length                                           | 12 month(s)         |
| Guideline Type                                            | Prior Authorization |
|                                                           |                     |

## Approval Criteria

**1** - ONE of the following risk factors for NSAID (non-steroidal anti-inflammatory drug)-induced adverse GI (gastrointestinal) events:

- Patient is greater than or equal to 65 years of age
- Prior history of peptic, gastric, or duodenal ulcer
- History of NSAID-related ulcer
- History of clinically significant GI bleeding
- Untreated or active H. Pylori (Helicobacter pylori) gastritis
- Concurrent use of oral corticosteroids (e.g., prednisone, prednisolone, dexamethasone)
- Concurrent use of anticoagulants (e.g., warfarin, heparin)
- Concurrent use of antiplatelets (e.g., aspirin including low-dose, clopidogrel)

**AND**

**2** - ONE of the following:

**2.1** Failure to THREE combinations of preferred\* NSAIDs, one of which must be celecoxib (generic Celebrex), taken concomitantly with preferred\* proton pump inhibitors, as confirmed by claims history or submitted medical records

**OR**

**2.2** History of contraindication or intolerance to ALL preferred\* NSAIDs and ALL preferred\* proton pump inhibitors (please specify contraindication or intolerance)

**AND**

**3** - Physician has provided rationale for needing to use fixed-dose combination therapy with Vimovo instead of taking individual products in combination

Notes

\*PDL links in Background.

## 2 . Background

### Benefit/Coverage/Program Information

**PDL Links:**

**CO:** <https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html>

**HI:** <https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html>

**MD:** <https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-cp-pharmacy.html>

**NJ:** <https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html>

**NY/NY EPP:** <https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html>

**PA CHIP:** <https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP>

**RI:** <https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html>

**NM:** <https://www.uhcprovider.com/en/health-plans-by-state/new-mexico-health-plans/nm-comm-plan-home/nm-cp-pharmacy.html>

### 3 . Revision History

| Date     | Notes                                                                                                                                  |
|----------|----------------------------------------------------------------------------------------------------------------------------------------|
| 7/3/2025 | Combined formularies. No changes to clinical criteria. Updated backg round section to include PDL link for NM. Minor cosmetic updates. |

Duopa



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-426232                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Guideline Name</b> | Duopa                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 11/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                    |                       |
|--------------------|-----------------------|
| Product Name:Duopa |                       |
| Approval Length    | 12 month(s)           |
| Therapy Stage      | Initial Authorization |
| Guideline Type     | Prior Authorization   |

**Approval Criteria**

1 - Diagnosis of advanced Parkinson's disease

**AND**

2 - Patient experiences a wearing “off” phenomenon that cannot be managed by increasing the dose of oral levodopa

**AND**

3 - Has undergone or has planned placement of a procedurally-placed tube

**AND**

4 - Prescribed by or in consultation with a neurologist

|                                                                                                         |                     |
|---------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Duopa                                                                                      |                     |
| Approval Length                                                                                         | 12 month(s)         |
| Therapy Stage                                                                                           | Reauthorization     |
| Guideline Type                                                                                          | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p>1 - Documentation of positive clinical response to Duopa therapy</p> |                     |

## 2 . Revision History

| Date       | Notes                                                  |
|------------|--------------------------------------------------------|
| 10/20/2025 | Combined formularies. No changes to clinical criteria. |



Dupixent



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-398306                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Guideline Name</b> | Dupixent                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 11/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                        |                       |
|------------------------|-----------------------|
| Product Name: Dupixent |                       |
| Diagnosis              | Atopic Dermatitis     |
| Approval Length        | 12 month(s)           |
| Therapy Stage          | Initial Authorization |
| Guideline Type         | Prior Authorization   |

## **Approval Criteria**

**1** - Diagnosis of moderate-to-severe chronic atopic dermatitis

**AND**

**2** - ONE of the following:

**2.1** Failure to TWO of the following therapeutic classes of topical therapies as confirmed by claims history or submission of medical records:

- One medium, high, or very-high potency topical corticosteroid [e.g., mometasone furoate (generic Elocon), fluocinolone acetonide (generic Synalar), fluocinonide (generic Lidex)] (see Table 1 in Background)
- One topical calcineurin inhibitor [e.g., pimecrolimus (generic Elidel), tacrolimus (generic Protopic)]
- Eucrisa (crisaborole)

**OR**

**2.2** History of contraindication or intolerance to ALL of the following therapeutic classes of topical therapies (please specify contraindication or intolerance):

- One medium, high, or very-high potency topical corticosteroid [e.g., mometasone furoate (generic Elocon), fluocinolone acetonide (generic Synalar), fluocinonide (generic Lidex)] (see Table 1 in Background)
- One topical calcineurin inhibitor [e.g., pimecrolimus (generic Elidel), tacrolimus (generic Protopic)]
- Eucrisa (crisaborole)

**OR**

**2.3** Patient is currently on Dupixent therapy as confirmed by claims history or submission of medical records

**AND**



**3** - Patient is NOT receiving Dupixent in combination with either of the following for treatment of the same indication:

- Biologic immunomodulator [e.g., Adbry (tralokinumab-ldrm), Nemluvio (nemolizumab-ilto)]
- Janus kinase inhibitor [e.g., Rinvoq (upadacitinib), Xeljanz/XR (tofacitinib), Opzelura (topical ruxolitinib), Cibinqo (abrocitinib)]

**AND**

**4** - Prescribed by or in consultation with ONE of the following:

- Dermatologist
- Allergist
- Immunologist

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                     |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name: Dupixent                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                     |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Atopic Dermatitis   |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 12 month(s)         |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of positive clinical response to Dupixent therapy</p> <p><b>AND</b></p> <p><b>2</b> - Patient is NOT receiving Dupixent in combination with either of the following for treatment of the same indication:</p> <ul style="list-style-type: none"> <li>• Biologic immunomodulator [e.g., Adbry (tralokinumab-ldrm), Nemluvio (nemolizumab-ilto)]</li> <li>• Janus kinase inhibitor [e.g., Rinvoq (upadacitinib), Xeljanz/XR (tofacitinib), Opzelura (topical ruxolitinib), Cibinqo (abrocitinib)]</li> </ul> |                     |

**AND**

**3** - Prescribed by or in consultation with ONE of the following:

- Dermatologist
- Allergist
- Immunologist

**Product Name:**Dupixent

|                 |                       |
|-----------------|-----------------------|
| Diagnosis       | Asthma                |
| Approval Length | 12 month(s)           |
| Therapy Stage   | Initial Authorization |
| Guideline Type  | Prior Authorization   |

### **Approval Criteria**

**1** - Diagnosis of moderate-to-severe asthma

**AND**

**2** - ONE of the following:

**2.1** ALL of the following:

**2.1.1** Classification of asthma as uncontrolled or inadequately controlled as defined by at least ONE of the following:

- Poor symptom control [e.g., Asthma Control Questionnaire (ACQ) score consistently greater than 1.5 or Asthma Control Test (ACT) score consistently less than 20]
- Two or more bursts of systemic corticosteroids for at least 3 days each in the previous 12 months
- Asthma-related emergency treatment (e.g., emergency room visit, hospital admission, or unscheduled physician's office visit for nebulizer or other urgent treatment)
- Airflow limitation [e.g., after appropriate bronchodilator withhold forced expiratory volume in 1 second (FEV1) less than 80% predicted (in the face of reduced FEV1/forced vital capacity [FVC] defined as less than the lower limit of normal)]
- Patient is currently dependent on oral corticosteroids for the treatment of asthma

**AND**

**2.1.2** Dupixent will be used in combination with ONE of the following:

**2.1.2.1** ONE maximally-dosed (appropriately adjusted for age) combination inhaled corticosteroid (ICS)/long-acting beta2 agonist (LABA) [e.g., Advair/AirDuo Respiclick (fluticasone propionate/salmeterol), Symbicort (budesonide/formoterol), Breo Ellipta (fluticasone furoate/vilanterol)] (see Table 2 in Background)

**OR**

**2.1.2.2** Combination therapy including BOTH of the following:

- ONE maximally-dosed (appropriately adjusted for age) ICS product [e.g., ciclesonide (Alvesco), mometasone furoate (Asmanex), beclomethasone dipropionate (QVAR)] (see Table 2 in Background)
- ONE additional asthma controller medication [e.g., LABA - olodaterol (Striverdi) or indacaterol (Arcapta); leukotriene receptor antagonist - montelukast (Singulair); theophylline]

**AND**

**2.1.3** ONE of the following:

- Submission of medical records (e.g., chart notes, laboratory values, etc.) documenting that asthma is an eosinophilic phenotype as defined by a baseline (pre-dupilumab treatment) peripheral blood eosinophil level greater than or equal to 150 cells/microliter
- Patient is currently dependent on oral corticosteroids for the treatment of asthma

**OR**

**2.2** BOTH of the following:

**2.2.1** Patient is currently on Dupixent therapy as confirmed by claims history or submission of medical records

**AND**

**2.2.2** Dupixent will be used in combination with ONE of the following:

**2.2.2.1** ONE maximally-dosed (appropriately adjusted for age) combination inhaled corticosteroid (ICS)/long-acting beta2 agonist (LABA) [e.g., Advair/AirDuo Respiclick (fluticasone propionate/salmeterol), Symbicort (budesonide/formoterol), Breo Ellipta (fluticasone furoate/vilanterol)]

**OR**

**2.2.2.2** Combination therapy including BOTH of the following:

- ONE maximally-dosed (appropriately adjusted for age) ICS product [e.g., ciclesonide (Alvesco), mometasone furoate (Asmanex), beclomethasone dipropionate (QVAR)]
- ONE additional asthma controller medication [e.g., LABA - olodaterol (Striverdi) or indacaterol (Arcapta); leukotriene receptor antagonist – montelukast (Singulair); theophylline]

**AND**

**3** - Patient is NOT receiving Dupixent in combination with any of the following for treatment of the same indication:

- Anti-interleukin-5 therapy [e.g., Nucala (mepolizumab), Cinqair (reslizumab), Fasenra (benralizumab)]
- Anti-IgE (immunoglobulin E) therapy [e.g., Xolair (omalizumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

**AND**

**4** - Prescribed by or in consultation with ONE of the following:

- Allergist
- Immunologist
- Pulmonologist

|                        |             |
|------------------------|-------------|
| Product Name: Dupixent |             |
| Diagnosis              | Asthma      |
| Approval Length        | 12 month(s) |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                     |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of positive clinical response to Dupixent therapy as demonstrated by at least ONE of the following:</p> <ul style="list-style-type: none"> <li>• Reduction in the frequency of exacerbations</li> <li>• Decreased utilization of rescue medications</li> <li>• Increase in percent predicted forced expiratory volume in 1 second (FEV1) from pretreatment baseline</li> <li>• Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.)</li> <li>• Reduction in oral corticosteroid requirements</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Dupixent will be used in combination with ONE of the following:</p> <p><b>2.1</b> ONE maximally-dosed (appropriately adjusted for age) combination inhaled corticosteroid (ICS)/long-acting beta2 agonist (LABA) [e.g., Advair/AirDuo Respiclick (fluticasone propionate/salmeterol), Symbicort (budesonide/formoterol), Breo Ellipta (fluticasone furoate/vilanterol)]</p> <p style="text-align: center;"><b>OR</b></p> <p><b>2.2</b> Combination therapy including BOTH of the following:</p> <ul style="list-style-type: none"> <li>• ONE maximally-dosed (appropriately adjusted for age) ICS product [e.g., ciclesonide (Alvesco), mometasone furoate (Asmanex), beclomethasone dipropionate (QVAR)]</li> <li>• ONE additional asthma controller medication [e.g., LABA - olodaterol (Striverdi) or indacaterol (Arcapta); leukotriene receptor antagonist – montelukast (Singulair); theophylline]</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Patient is NOT receiving Dupixent in combination with any of the following for treatment of the same indication:</p> |                     |

- Anti-interleukin-5 therapy [e.g., Nucala (mepolizumab), Cinqair (reslizumab), Fasenra (benralizumab)]
- Anti-IgE (immunoglobulin E) therapy [e.g., Xolair (omalizumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

**AND**

**4** - Prescribed by or in consultation with ONE of the following:

- Allergist
- Immunologist
- Pulmonologist

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                             |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|
| Product Name: Dupixent                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                             |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Chronic Rhinosinusitis with Nasal Polyposis |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 12 month(s)                                 |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Initial Authorization                       |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Prior Authorization                         |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - ONE of the following:</p> <p><b>1.1</b> Diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP) defined by ALL of the following:</p> <p><b>1.1.1</b> TWO or more of the following symptoms for longer than 12 weeks duration:</p> <ul style="list-style-type: none"> <li>• Nasal mucopurulent discharge</li> <li>• Nasal obstruction, blockage, or congestion</li> <li>• Facial pain, pressure, and/or fullness</li> <li>• Reduction or loss of sense of smell</li> </ul> <p><b>AND</b></p> <p><b>1.1.2</b> ONE of the following findings using nasal endoscopy and/or sinus computed tomography (CT):</p> |                                             |

- Purulent mucus or edema in the middle meatus or ethmoid regions
- Polyps in the nasal cavity or the middle meatus
- Radiographic imaging demonstrating mucosal thickening or partial or complete opacification of paranasal sinuses

**AND**

**1.1.3 ONE of the following:**

- Presence of bilateral nasal polyposis
- Patient has previously required surgical removal of bilateral nasal polyps

**AND**

**1.1.4 ONE of the following:**

**1.1.4.1 Patient has required prior sinus surgery**

**OR**

**1.1.4.2 Patient has required systemic corticosteroids (e.g., prednisone, methylprednisolone) for CRSwNP in the previous 2 years**

**OR**

**1.1.4.3 Patient has been unable to obtain symptom relief after trial of TWO of the following classes of agents:**

- Nasal saline irrigations
- Intranasal corticosteroids (e.g., fluticasone, mometasone, triamcinolone)
- Antileukotriene agents (e.g., montelukast, zafirlukast, zileuton)

**OR**

**1.2 BOTH of the following:**

- Diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP)

- Patient is currently on Dupixent therapy as confirmed by claims history or submission of medical records

**AND**

**2** - Patient will receive Dupixent as add-on maintenance therapy in combination with intranasal corticosteroids (e.g., fluticasone, mometasone, triamcinolone)

**AND**

**3** - Patient is NOT receiving Dupixent in combination with any of the following for treatment of the same indication:

- Anti-interleukin-5 therapy [e.g., Cinqair (reslizumab), Fasenra (benralizumab), Nucala (mepolizumab)]
- Anti-IgE therapy [e.g., Xolair (omalizumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

**AND**

**4** - Prescribed by or in consultation with ONE of the following:

- Allergist
- Immunologist
- Otolaryngologist
- Pulmonologist

|                                                                                                                   |                                             |
|-------------------------------------------------------------------------------------------------------------------|---------------------------------------------|
| Product Name: Dupixent                                                                                            |                                             |
| Diagnosis                                                                                                         | Chronic Rhinosinusitis with Nasal Polyposis |
| Approval Length                                                                                                   | 12 month(s)                                 |
| Therapy Stage                                                                                                     | Reauthorization                             |
| Guideline Type                                                                                                    | Prior Authorization                         |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of positive clinical response to Dupixent therapy</p> |                                             |



**AND**

**2** - Patient will continue to receive Dupixent as add-on maintenance therapy in combination with intranasal corticosteroids (e.g., fluticasone, mometasone, triamcinolone), as confirmed by claims history or submission of medical records

**AND**

**3** - Patient is NOT receiving Dupixent in combination with any of the following for treatment of the same indication:

- Anti-interleukin-5 therapy [e.g., Cinqair (reslizumab), Fasenra (benralizumab), Nucala (mepolizumab)]
- Anti-IgE therapy [e.g., Xolair (omalizumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

**AND**

**4** - Prescribed by or in consultation with ONE of the following:

- Allergist
- Immunologist
- Otolaryngologist
- Pulmonologist

|                                                                                         |                          |
|-----------------------------------------------------------------------------------------|--------------------------|
| Product Name: Dupixent                                                                  |                          |
| Diagnosis                                                                               | Eosinophilic Esophagitis |
| Approval Length                                                                         | 12 month(s)*             |
| Therapy Stage                                                                           | Initial Authorization    |
| Guideline Type                                                                          | Prior Authorization      |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of eosinophilic esophagitis</p> |                          |

**AND**

**2** - Patient is experiencing symptoms related to esophageal dysfunction (e.g., dysphagia, food impaction, chest pain that is often centrally located and may not respond to antacids, gastroesophageal reflux disease-like symptoms/refractory heartburn, upper abdominal pain)

**AND**

**3** - Submission of medical records (e.g., chart notes, laboratory values, etc.) documenting eosinophil-predominant inflammation on esophageal biopsy, consisting of a peak value of 15 or more intraepithelial eosinophils per high power field (HPF) [or 60 eosinophils per mm<sup>2</sup> (square millimeters)]

**AND**

**4** - Secondary causes of esophageal eosinophilia have been ruled out

**AND**

**5** - Mucosal eosinophilia is isolated to the esophagus and symptoms have persisted after an 8-week trial of at least ONE of the following, as confirmed by claims history or submission of medical records:

- Proton pump inhibitors (e.g., pantoprazole, omeprazole)
- Topical (esophageal) corticosteroids (e.g., budesonide, fluticasone)

**AND**

**6** - Patient is NOT receiving Dupixent in combination with any of the following for treatment of the same indication:

- Anti-interleukin-5 therapy [e.g., Cinqair (reslizumab), Fasenra (benralizumab), Nucala (mepolizumab)]
- Anti-IgE therapy [e.g., Xolair (omalizumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

**AND**

**7** - Prescribed by or in consultation with ONE of the following:

- Allergist
- Gastroenterologist

Notes

\*If clinical criteria is met, enter a GPI-10 authorization with a MDD of 0 .3 mL.

Product Name: Dupixent

Diagnosis Eosinophilic Esophagitis

Approval Length 12 month(s)\*

Therapy Stage Reauthorization

Guideline Type Prior Authorization

### Approval Criteria

**1** - Documentation of positive clinical response to Dupixent therapy as evidenced by improvement of at least ONE of the following from baseline:

- Symptoms (e.g., dysphagia, chest pain, heartburn)
- Histologic measures (e.g., esophageal intraepithelial eosinophil count)
- Endoscopic measures (e.g., edema, furrows, exudates, rings, strictures)

**AND**

**2** - Patient is NOT receiving Dupixent in combination with any of the following for treatment of the same indication:

- Anti-interleukin-5 therapy [e.g., Cinqair (reslizumab), Fasenra (benralizumab), Nucala (mepolizumab)]
- Anti-IgE therapy [e.g., Xolair (omalizumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

**AND**

|                                                                                    |                                                                                   |
|------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|
| <b>3 - Prescribed by or in consultation with a gastroenterologist or allergist</b> |                                                                                   |
| Notes                                                                              | *If clinical criteria is met, enter a GPI-10 authorization with a MDD of 0 .3 mL. |

|                        |                       |
|------------------------|-----------------------|
| Product Name: Dupixent |                       |
| Diagnosis              | Prurigo Nodularis     |
| Approval Length        | 12 month(s)           |
| Therapy Stage          | Initial Authorization |
| Guideline Type         | Prior Authorization   |

  

**Approval Criteria**

1 - Diagnosis of prurigo nodularis

**AND**

2 - Patient has greater than or equal to 20 nodular lesions

**AND**

3 - ONE of the following:

**3.1** Failure to at least one previous prurigo nodularis treatment(s) (e.g., topical corticosteroids, topical calcineurin inhibitors, topical capsaicin) as confirmed by claims history or submission of medical records

**OR**

**3.2** History of contraindication or intolerance to all other prurigo nodularis treatment(s) (e.g., topical corticosteroids, topical calcineurin inhibitors, topical capsaicin) (please specify contraindication or intolerance)

**AND**

**4** - Patient is NOT receiving Dupixent in combination with either of the following for treatment of the same indication:

- Biologic immunomodulator [e.g., Adbry (tralokinumab-ldrm), Nemluvio (nemolizumab-ilto)]
- Janus kinase inhibitor [e.g., Rinvoq (upadacitinib), Xeljanz/XR (tofacitinib), Opzelura (topical ruxolitinib), Cibinqo (abrocitinib)]

**AND**

**5** - Prescribed by or in consultation with ONE of the following:

- Dermatologist
- Allergist
- Immunologist

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|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name: Dupixent                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                     |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Prurigo Nodularis   |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 12 month(s)         |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of positive clinical response to Dupixent therapy</p> <p><b>AND</b></p> <p><b>2</b> - Patient is NOT receiving Dupixent in combination with either of the following for treatment of the same indication:</p> <ul style="list-style-type: none"> <li>• Biologic immunomodulator [e.g., Adbry (tralokinumab-ldrm), Nemluvio (nemolizumab-ilto)]</li> <li>• Janus kinase inhibitor [e.g., Rinvoq (upadacitinib), Xeljanz/XR (tofacitinib), Opzelura (topical ruxolitinib), Cibinqo (abrocitinib)]</li> </ul> |                     |

**AND**

**3** - Prescribed by or in consultation with ONE of the following:

- Dermatologist
- Allergist
- Immunologist

**Product Name:**Dupixent

|                 |                                               |
|-----------------|-----------------------------------------------|
| Diagnosis       | Chronic Obstructive Pulmonary Disorder (COPD) |
| Approval Length | 12 month(s)                                   |
| Therapy Stage   | Initial Authorization                         |
| Guideline Type  | Prior Authorization                           |

**Approval Criteria**

**1** - Diagnosis of chronic obstructive pulmonary disorder (COPD)

**AND**

**2** - Submission of documentation (e.g., medical records, chart notes) of ALL of the following:

- Post-bronchodilator forced expiratory volume (FEV1) / forced vital capacity (FVC) ratio less than 0.7
- Post-bronchodilator FEV1 % predicted greater than or equal to 30% and less than or equal to 70%
- Patient has an eosinophilic phenotype defined by a baseline (pre-dupilumab treatment) peripheral blood eosinophil level greater than or equal to 300 cells/ $\mu$ L

**AND**

**3** - Uncontrolled or inadequately controlled COPD demonstrated by BOTH of the following:

**3.1** ONE of the following:

- Two or more COPD exacerbations in the previous year requiring treatment with systemic corticosteroids and/or antibiotics
- One or more COPD exacerbation(s) that resulted in hospitalization or observation for over 24 hours in an emergency department or urgent care facility in the past year

**AND**

**3.2** COPD exacerbation(s) occurred while receiving maintenance therapy with ONE of the following:

- Triple therapy with a long-acting muscarinic antagonist (LAMA), long-acting beta agonist (LABA), and inhaled corticosteroid (ICS) (e.g., Breztri Aerosphere, Trelegy Ellipta)
- Dual therapy with a LAMA and LABA (e.g., Anoro Ellipta, Bevespi Aerosphere, Stiolto Respimat) and a failure, contraindication, or intolerance to an inhaled corticosteroid (ICS)

**AND**

**4** - Symptoms of chronic productive cough for at least 3 months in the past year

**AND**

**5** - Dupixent will be used as add-on maintenance therapy with ONE of the following:

- Triple therapy with a long-acting muscarinic antagonist (LAMA), long-acting beta agonist (LABA), and inhaled corticosteroid (ICS) (e.g., Breztri Aerosphere, Trelegy Ellipta)
- Dual therapy with a LAMA and LABA (e.g., Anoro Ellipta, Bevespi Aerosphere, Stiolto Respimat) and a failure, contraindication, or intolerance to an inhaled corticosteroid (ICS)

**AND**

**6** - Patient is NOT receiving Dupixent in combination with any of the following for treatment of the same indication:

- Anti-interleukin-5 therapy [e.g., Nucala (mepolizumab), Cinqair (reslizumab), Fasenra (benralizumab)]
- Anti-IgE therapy [e.g., Xolair (omalizumab)]

- Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

**AND**

**7** - Prescribed by or in consultation with ONE of the following:

- Allergist
- Immunologist
- Pulmonologist

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|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|
| Product Name: Dupixent                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                               |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Chronic Obstructive Pulmonary Disorder (COPD) |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 12 month(s)                                   |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Reauthorization                               |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Prior Authorization                           |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of a positive clinical response to Dupixent therapy as demonstrated by at least ONE of the following:</p> <ul style="list-style-type: none"> <li>• Reduction in the frequency of COPD exacerbations</li> <li>• Increase in percent predicted FEV1 from pretreatment baseline</li> <li>• Reduction in severity or frequency of COPD-related symptoms (e.g., dyspnea, wheezing, cough, sputum volume, decrease in sputum purulence)</li> <li>• Reduction in oral corticosteroid requirements</li> </ul> <p><b>AND</b></p> <p><b>2</b> - Dupixent will be used as add-on maintenance therapy with ONE of the following:</p> <ul style="list-style-type: none"> <li>• Triple therapy with a long-acting muscarinic antagonist (LAMA), long-acting beta agonist (LABA), and inhaled corticosteroid (ICS) (e.g., Breztri Aerosphere, Trelegy Ellipta)</li> <li>• Dual therapy with a LAMA and LABA (e.g., Anoro Ellipta, Bevespi Aerosphere, Stiolto Respimat) and a failure, contraindication, or intolerance to an inhaled corticosteroid (ICS)</li> </ul> |                                               |



**AND**

**3** - Patient is NOT receiving Dupixent in combination with any of the following for treatment of the same indication:

- Anti-interleukin-5 therapy [e.g., Nucala (mepolizumab), Cinqair (reslizumab), Fasenra (benralizumab)]
- Anti-IgE therapy [e.g., Xolair (omalizumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

**AND**

**4** - Prescribed by or in consultation with ONE of the following:

- Allergist
- Immunologist
- Pulmonologist

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|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|
| Product Name: Dupixent                                                                                                                                                                                                                                                                                                                                                                                                                              |                               |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                           | Chronic Spontaneous Urticaria |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                     | 12 month(s)                   |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                       | Initial Authorization         |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                      | Prior Authorization           |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of chronic spontaneous urticaria</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - ONE of the following:</p> <p><b>2.1</b> Patient remains symptomatic despite at least a 2-week trial and failure of two H1-antihistamines [e.g., Allegra (fexofenadine), Benadryl (diphenhydramine), Claritin (loratadine)]* (confirmed by claims history or submitted medical records)</p> |                               |

**OR**

**2.2** Patient remains symptomatic despite at least a 2-week trial and failure of BOTH of the following taken in combination (confirmed by claims history or submitted medical records):

**2.2.1** Second generation H1-antihistamine [e.g., Allegra (fexofenadine), Claritin (loratadine), Zyrtec (cetirizine)]

**AND**

**2.2.2** ONE of the following:

- Different second generation H1-antihistamine [e.g., Allegra (fexofenadine), Claritin (loratadine), Zyrtec (cetirizine)]
- First generation H1-antihistamine [e.g., Benadryl (diphenhydramine), Chlor-Trimeton (chlorpheniramine), Vistaril (hydroxyzine)]\*
- H2-antihistamine [e.g., Pepcid (famotidine), Tagamet HB (cimetidine), Zantac (ranitidine)]
- Leukotriene modifier [e.g., Singulair (montelukast)]

**OR**

**2.3** History of contraindication or intolerance to ONE of the following (please specify contraindication or intolerance)

**2.3.1** Two H1-antihistamines [e.g., Allegra (fexofenadine), Benadryl (diphenhydramine), Claritin (loratadine)]\*

**OR**

**2.3.2** BOTH of the following taken in combination:

**2.3.2.1** Second generation H1-antihistamine [e.g., Allegra (fexofenadine), Claritin (loratadine), Zyrtec (cetirizine)]

**AND**

**2.3.2.2** ONE of the following:

- Different second generation H1-antihistamine [e.g., Allegra (fexofenadine), Claritin (loratadine), Zyrtec (cetirizine)]
- First generation H1-antihistamine [e.g., Benadryl (diphenhydramine), Chlor-Trimeton (chlorpheniramine), Vistaril (hydroxyzine)]\*
- H2-antihistamine [e.g., Pepcid (famotidine), Tagamet HB (cimetidine), Zantac (ranitidine)]
- Leukotriene modifier [e.g., Singulair (montelukast)]

**AND**

**3** - Patient is NOT receiving Dupixent in combination with Xolair (omalizumab) for treatment of the same indication

**AND**

**4** - Prescribed by or in consultation with ONE of the following:

- Allergist
- Dermatologist
- Immunologist

|       |                                                                                                                                                                                                                                           |
|-------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Notes | *Patients 65 years of age and older in whom first generation H1-antihistamines are considered high risk medications to be avoided (e.g., Beers criteria, HEDIS) should be directed to try alternatives that are not considered high risk. |
|-------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                                                                                                                                                                            |                               |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|
| Product Name: Dupixent                                                                                                                                                     |                               |
| Diagnosis                                                                                                                                                                  | Chronic Spontaneous Urticaria |
| Approval Length                                                                                                                                                            | 12 month(s)                   |
| Therapy Stage                                                                                                                                                              | Reauthorization               |
| Guideline Type                                                                                                                                                             | Prior Authorization           |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of positive clinical response to Dupixent therapy (e.g., reduction in exacerbations, itch severity, hives)</p> |                               |

**AND**

**2** - Patient is NOT receiving Dupixent in combination with Xolair (omalizumab) for treatment of the same indication

**AND**

**3** - Prescribed by or in consultation with ONE of the following:

- Allergist
- Dermatologist
- Immunologist

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|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Dupixent                                                                                                                                                                                                                                                                                                        |                       |
| Diagnosis                                                                                                                                                                                                                                                                                                                    | Bullous Pemphigoid    |
| Approval Length                                                                                                                                                                                                                                                                                                              | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                               | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of bullous pemphigoid</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Prescribed by or in consultation with ONE of the following:</p> <ul style="list-style-type: none"> <li>• Dermatologist</li> <li>• Allergist</li> <li>• Immunologist</li> </ul> |                       |

|                       |
|-----------------------|
| Product Name:Dupixent |
|-----------------------|

|                                                                                                                                                                                                                                                                                                                                                              |                     |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Diagnosis                                                                                                                                                                                                                                                                                                                                                    | Bullous Pemphigoid  |
| Approval Length                                                                                                                                                                                                                                                                                                                                              | 12 month(s)         |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                               | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of positive clinical response to Dupixent therapy</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Prescribed by or in consultation with ONE of the following:</p> <ul style="list-style-type: none"> <li>• Dermatologist</li> <li>• Allergist</li> <li>• Immunologist</li> </ul> |                     |

## 2 . Background

| Benefit/Coverage/Program Information                   |                                      |                         |              |
|--------------------------------------------------------|--------------------------------------|-------------------------|--------------|
| Table 1: Relative potencies of topical corticosteroids |                                      |                         |              |
| Class                                                  | Drug                                 | Dosage Form             | Strength (%) |
| Very high potency                                      | Augmented betamethasone dipropionate | Ointment, gel           | 0.05         |
|                                                        | Clobetasol propionate                | Cream, foam, ointment   | 0.05         |
|                                                        | Diflorasone diacetate                | Ointment                | 0.05         |
|                                                        | Halobetasol propionate               | Cream, ointment         | 0.05         |
|                                                        | Amcinonide                           | Cream, lotion, ointment | 0.1          |

|                      |                                      |                                 |       |
|----------------------|--------------------------------------|---------------------------------|-------|
| High Potency         | Augmented betamethasone dipropionate | Cream, lotion                   | 0.05  |
|                      | Betamethasone dipropionate           | Cream, foam, ointment, solution | 0.05  |
|                      | Desoximetasone                       | Cream, ointment                 | 0.25  |
|                      | Desoximetasone                       | Gel                             | 0.05  |
|                      | Diflorasone diacetate                | Cream                           | 0.05  |
|                      | tridifloronide                       | Cream, gel, ointment, solution  | 0.05  |
|                      | Halcinonide                          | Cream, ointment                 | 0.1   |
|                      | Mometasone furoate                   | Ointment                        | 0.1   |
|                      | Triamcinolone acetonide              | Cream, ointment                 | 0.5   |
| Medium potency       | Betamethasone valerate               | Cream, foam, lotion, ointment   | 0.1   |
|                      | Clocortolone pivalate                | Cream                           | 0.1   |
|                      | Desoximetasone                       | Cream                           | 0.05  |
|                      | Fluocinolone acetonide               | Cream, ointment                 | 0.025 |
|                      | Flurandrenolide                      | Cream, ointment, lotion         | 0.05  |
|                      | Fluticasone propionate               | Cream                           | 0.05  |
|                      | Fluticasone propionate               | Ointment                        | 0.005 |
|                      | Mometasone furoate                   | Cream, lotion                   | 0.1   |
|                      | Triamcinolone acetonide              | Cream, ointment, lotion         | 0.1   |
| Lower-medium potency | Hydrocortisone butyrate              | Cream, ointment, solution       | 0.1   |
|                      | Hydrocortisone probutate             | Cream                           | 0.1   |
|                      | Hydrocortisone valerate              | Cream, ointment                 | 0.2   |
|                      | Prednicarbate                        | Cream                           | 0.1   |
| Low potency          | Alclometasone dipropionate           | Cream, ointment                 | 0.05  |
|                      | Desonide                             | Cream, gel, foam, ointment      | 0.05  |

|                |                        |                                   |              |
|----------------|------------------------|-----------------------------------|--------------|
|                | Fluocinolone acetonide | Cream, solution                   | 0.01         |
|                | Dexamethasone          | Cream                             | 0.1          |
| Lowest potency | Hydrocortisone         | Cream, lotion, ointment, solution | 0.25, 0.5, 1 |
|                | Hydrocortisone acetate | Cream, ointment                   | 0.5-1        |

**Table 2: Low, medium, and high daily doses of inhaled corticosteroids. Adults and adolescents (12 years of age and older)**

| Drug                              | Daily dose (mcg) |            |       |
|-----------------------------------|------------------|------------|-------|
|                                   | Low              | Medium     | High  |
| Beclomethasone dipropionate (CFC) | 200-500          | >500-1000  | >1000 |
| Beclomethasone dipropionate (HFA) | 100-200          | >200-400   | >400  |
| Budesonide DPI                    | 200-400          | >400-800   | >800  |
| Ciclesonide (HFA)                 | 80-160           | >160-320   | >320  |
| Fluticasone furoate (DPI)         | 100              | N/A        | 200   |
| Fluticasone propionate (DPI)      | 100-250          | >250-500   | >500  |
| Fluticasone propionate (HFA)      | 100-250          | >250-500   | >500  |
| Mometasone furoate                | 110-220          | >220-440   | >440  |
| Triamcinolone acetonide           | 400-1000         | >1000-2000 | >2000 |

### 3 . Revision History

| Date       | Notes                                                                                 |
|------------|---------------------------------------------------------------------------------------|
| 10/15/2025 | Added criteria for the new indication for bullous pemphigoid. Minor cosmetic updates. |

Duvyzat



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-375413                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Guideline Name</b> | Duvyzat                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 10/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                      |                       |
|----------------------|-----------------------|
| Product Name:Duvyzat |                       |
| Approval Length      | 12 month(s)           |
| Therapy Stage        | Initial Authorization |
| Guideline Type       | Prior Authorization   |



**Approval Criteria**

**1** - Diagnosis of Duchenne muscular dystrophy (DMD)

**AND**

**2** - Diagnosis confirmed by the presence of a mutation in the DMD gene

**AND**

**3** - Patient is 6 years of age or older

**AND**

**4** - Submission of medical records (e.g., chart notes) confirming that the patient is ambulatory without needing an assistive device (e.g., without side-by-side assist, cane, walker, wheelchair, etc.)

**AND**

**5** - Patient has been or will be established on a stable corticosteroid regimen

**AND**

**6** - Prescribed by, or in consultation with, a pediatric neuromuscular specialist with expertise in the treatment of DMD

**AND**

**7** - Patient has not received gene therapy for DMD [e.g., Elevidys (delandistrogene moxparvovec-rokl)]

**AND**

**8** - Patient will not receive Duvyzat in combination with exon-skipping therapies for DMD [e.g., Amondys (casimersen), Exondys 51 (eteplisen), Viltepso (viltolarsen), Vyondys 53 (golodirsen)]

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                     |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Duvyzat                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                     |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 12 month(s)         |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Physician attestation that patient would benefit from continued administration</p> <p><b>AND</b></p> <p><b>2</b> - Submission of medical records (e.g., chart notes) confirming that the patient is ambulatory without needing an assistive device (e.g., without side-by-side assist, cane, walker, wheelchair, etc.)</p> <p><b>AND</b></p> <p><b>3</b> - Patient continues to receive concomitant corticosteroid regimen</p> <p><b>AND</b></p> <p><b>4</b> - Prescribed by, or in consultation with, a pediatric neuromuscular specialist with expertise in the treatment of DMD</p> <p><b>AND</b></p> |                     |

**5** - Patient has not received gene therapy for DMD [e.g., Elevidys (delandistrogene moxparvovec-rokl)]

**AND**

**6** - Patient will not receive Duvyzat in combination with exon-skipping therapies for DMD [e.g., Amondys (casimersen), Exondys 51 (eteplirsen), Viltepso (viltolarsen), Vyondys 53 (golodirsen)]

## 2 . Revision History

| Date      | Notes                                                  |
|-----------|--------------------------------------------------------|
| 8/25/2025 | Combined formularies. No changes to clinical criteria. |

Ebglyss



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-230291                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Guideline Name</b> | Ebglyss                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 6/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                      |                       |
|----------------------|-----------------------|
| Product Name:Ebglyss |                       |
| Approval Length      | 12 month(s)           |
| Therapy Stage        | Initial Authorization |
| Guideline Type       | Prior Authorization   |

## **Approval Criteria**

**1** - Diagnosis of moderate-to-severe chronic atopic dermatitis

**AND**

**2** - One of the following:

**2.1** Inadequate response to TWO of the following therapeutic classes of topical therapies as confirmed by claims history or submission of medical records:

- One medium, high or very-high potency topical corticosteroid [e.g., mometasone furoate (generic Elocon), fluocinolone acetonide (generic Synalar), fluocinonide (generic Lidex)]\*
- One topical calcineurin inhibitor [e.g., pimecrolimus (generic Elidel), tacrolimus (generic Protopic)]
- Eucrisa (crisaborole)

**OR**

**2.2** History of contraindication or intolerance to ALL of the following therapeutic classes of topical therapies (please specify contraindication or intolerance):

- One medium, high or very-high potency topical corticosteroid [e.g., mometasone furoate (generic Elocon), fluocinolone acetonide (generic Synalar), fluocinonide (generic Lidex)]\*
- One topical calcineurin inhibitor [e.g., pimecrolimus (generic Elidel), tacrolimus (generic Protopic)]
- Eucrisa (crisaborole)

**OR**

**2.3** Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of atopic dermatitis as documented by claims history or submission of medical records [e.g., Adbry (tralokinumab-ldrm), Cibinqo (abrocitinib), Dupixent (dupilumab), Ebglyss (lebrikizumab-lbkz), Opzelura (ruxolitinib), Rinvoq (upadacitinib)]

**AND**

**3 - One of the following:**

**3.1** Failure to BOTH of the following as confirmed by claims history or submission of medical records:

- Adbry (tralokinumab-ldrm)
- Dupixent (dupilumab)

**OR**

**3.2** History of contraindication or intolerance to BOTH of the following (please specify contraindication or intolerance):

- Adbry (tralokinumab-ldrm)
- Dupixent (dupilumab)

**OR**

**3.3** Patient is currently on Ebglyss therapy as confirmed by claims history or submission of medical records

**AND**

**4 - Patient is NOT receiving Ebglyss in combination with either of the following:**

- Biologic immunomodulator [e.g., Adbry (tralokinumab-ldrm), Dupixent (dupilumab), Nemluvio (nemolizumab-ilto)]
- Janus kinase inhibitor [e.g., Cibinqo (abrocitinib), Opzelura (topical ruxolitinib), Rinvoq (upadacitinib), Xeljanz/XR (tofacitinib)]

**AND**

**5 - Prescribed by or in consultation with one of the following:**

- Dermatologist
- Allergist
- Immunologist

Notes

\*See Table 1 for relative potencies of topical corticosteroids.

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                     |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Ebglyss                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                     |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 12 month(s)         |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of positive clinical response to Ebglyss therapy</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Patient is NOT receiving Ebglyss in combination with either of the following:</p> <ul style="list-style-type: none"> <li>• Biologic immunomodulator [e.g., Adbry (tralokinumab-ldrm), Dupixent (dupilumab), Nemluvio (nemolizumab-ilto)]</li> <li>• Janus kinase inhibitor [e.g., Cibinqo (abrocitinib), Opzelura (topical ruxolitinib), Rinvoq (upadacitinib), Xeljanz/XR (tofacitinib)]</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Prescribed by or in consultation with one of the following:</p> <ul style="list-style-type: none"> <li>• Dermatologist</li> <li>• Allergist</li> <li>• Immunologist</li> </ul> |                     |

## 2 . Background

|                                                               |
|---------------------------------------------------------------|
| <b>Benefit/Coverage/Program Information</b>                   |
| <b>Table 1: Relative potencies of topical corticosteroids</b> |

| Class                | Drug                                 | Dosage Form                       | Strength (%) |
|----------------------|--------------------------------------|-----------------------------------|--------------|
| Very high potency    | Augmented betamethasone dipropionate | Ointment, gel                     | 0.05         |
|                      | Clobetasol propionate                | Cream, foam, ointment             | 0.05         |
|                      | Diflorasone diacetate                | Ointment                          | 0.05         |
|                      | Halobetasol propionate               | Cream, ointment                   | 0.05         |
| High Potency         | Amcinonide                           | Cream, lotion, ointment           | 0.1          |
|                      | Augmented betamethasone dipropionate | Cream, lotion                     | 0.05         |
|                      | Betamethasone dipropionate           | Cream, foam, ointment, solution   | 0.05         |
|                      | Desoximetasone                       | Cream, ointment                   | 0.25         |
|                      | Desoximetasone                       | Gel                               | 0.05         |
|                      | Diflorasone diacetate                | Cream                             | 0.05         |
|                      | tridifloronide                       | Cream, gel, ointment, solution    | 0.05         |
|                      | Halcinonide                          | Cream, ointment                   | 0.1          |
|                      | Mometasone furoate                   | Ointment                          | 0.1          |
| Medium potency       | Triamcinolone acetonide              | Cream, ointment                   | 0.5          |
|                      | Betamethasone valerate               | Cream, foam, lotion, ointment     | 0.1          |
|                      | Clocortolone pivalate                | Cream                             | 0.1          |
|                      | Desoximetasone                       | Cream                             | 0.05         |
|                      | Fluocinolone acetonide               | Cream, ointment                   | 0.025        |
|                      | Flurandrenolide                      | Cream, ointment, lotion           | 0.05         |
|                      | Fluticasone propionate               | Cream                             | 0.05         |
|                      | Fluticasone propionate               | Ointment                          | 0.005        |
|                      | Mometasone furoate                   | Cream, lotion                     | 0.1          |
| Lower-medium potency | Triamcinolone acetonide              | Cream, ointment, lotion           | 0.1          |
|                      | Hydrocortisone butyrate              | Cream, ointment, solution         | 0.1          |
|                      | Hydrocortisone probutate             | Cream                             | 0.1          |
|                      | Hydrocortisone valerate              | Cream, ointment                   | 0.2          |
| Low potency          | Prednicarbate                        | Cream                             | 0.1          |
|                      | Alclometasone dipropionate           | Cream, ointment                   | 0.05         |
|                      | Desonide                             | Cream, gel, foam, ointment        | 0.05         |
| Lowest potency       | Fluocinolone acetonide               | Cream, solution                   | 0.01         |
|                      | Dexamethasone                        | Cream                             | 0.1          |
|                      | Hydrocortisone                       | Cream, lotion, ointment, solution | 0.25, 0.5, 1 |



|                        |                 |       |
|------------------------|-----------------|-------|
| Hydrocortisone acetate | Cream, ointment | 0.5-1 |
|------------------------|-----------------|-------|

### 3 . Revision History

| Date     | Notes |
|----------|-------|
| 4/3/2025 | New   |

Egrifta



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-219298                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Guideline Name</b> | Egrifta                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania (ACUPA)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 5/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                         |             |
|-------------------------|-------------|
| Product Name:Egrifta SV |             |
| Approval Length         | 12 month(s) |

|                                                                                                                     |                     |
|---------------------------------------------------------------------------------------------------------------------|---------------------|
| Guideline Type                                                                                                      | Prior Authorization |
| <b>Approval Criteria</b><br><br><b>1</b> - Diagnosis of human immunodeficiency virus (HIV)-associated lipodystrophy |                     |

## 2 . Revision History

| Date      | Notes                                                  |
|-----------|--------------------------------------------------------|
| 3/19/2025 | Combined formularies. No changes to clinical criteria. |

Ekterly



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-406203                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Guideline Name</b> | Ekterly                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Michigan (ACUMI)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 11/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                      |                       |
|----------------------|-----------------------|
| Product Name:Ekterly |                       |
| Approval Length      | 12 month(s)           |
| Therapy Stage        | Initial Authorization |

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Prior Authorization |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1 - Diagnosis of hereditary angioedema (HAE) as confirmed by ONE of the following:</b></p> <p><b>1.1</b> C1 inhibitor (C1-INH) deficiency or dysfunction (Type I or II HAE) as documented by ONE of the following (per laboratory standard):</p> <ul style="list-style-type: none"> <li>• C1-INH antigenic level below the lower limit of normal</li> <li>• C1-INH functional level below the lower limit of normal</li> </ul> <p style="text-align: center;"><b>OR</b></p> <p><b>1.2</b> HAE with normal C1 inhibitor levels and ONE of the following:</p> <ul style="list-style-type: none"> <li>• Confirmed presence of variant(s) in the gene(s) for factor XII, angiotensin-1, plasminogen-1, kininogen-1, myoferlin, or heparan sulfate-glucosamine 3-O-sulfotransferase 6</li> <li>• Recurring angioedema attacks that are refractory to high-dose antihistamines with confirmed family history of angioedema</li> <li>• Recurring angioedema attacks that are refractory to high-dose antihistamines with unknown background de-novo mutation(s) (i.e., no family history) (HAE-unknown)</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>2 - Prescribed for the acute treatment of HAE attacks</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>3 - Not used in combination with other products indicated for the acute treatment of HAE attacks (e.g., Berinert, Firazyr, icatibant, Kalbitor, Ruconest, Sajazir)</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>4 - Prescribed by ONE of the following:</b></p> <ul style="list-style-type: none"> <li>• Immunologist</li> </ul> |                     |

- Allergist

|                      |                     |
|----------------------|---------------------|
| Product Name:Ekterly |                     |
| Approval Length      | 12 month(s)         |
| Therapy Stage        | Reauthorization     |
| Guideline Type       | Prior Authorization |

**Approval Criteria**

1 - Documentation of positive clinical response to Ekterly therapy

**AND**

2 - Prescribed for the acute treatment of HAE (hereditary angioedema) attacks

**AND**

3 - Not used in combination with other products indicated for the acute treatment of HAE attacks (e.g., Berinert, Firazyr, icatibant, Kalbitor, Ruconest, Sajazir)

**AND**

4 - Prescribed by ONE of the following:

- Immunologist
- Allergist

## 2 . Revision History

| Date      | Notes        |
|-----------|--------------|
| 10/7/2025 | New Program. |



Elmiron



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-117347                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Guideline Name</b> | Elmiron                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>•</li> <li>•</li> <li>•</li> <li>•</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 1/1/2023 |
|-----------------|----------|

## 1 . Criteria

|                      |                     |
|----------------------|---------------------|
| Product Name:Elmiron |                     |
| Approval Length      | 12 month(s)         |
| Guideline Type       | Prior Authorization |



**Approval Criteria**

1 - Patient has a documented diagnosis of bladder pain or discomfort associated with interstitial cystitis

**2 . Revision History**

| Date       | Notes                                  |
|------------|----------------------------------------|
| 11/30/2022 | Updated formularies and indication box |

Emflaza



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-161230                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Guideline Name</b> | Emflaza                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 1/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                                                  |                             |
|--------------------------------------------------|-----------------------------|
| Product Name: Brand Emflaza, generic deflazacort |                             |
| Diagnosis                                        | Duchenne Muscular Dystrophy |
| Guideline Type                                   | Prior Authorization         |
| Approval Criteria                                |                             |

**1** - Published clinical evidence shows Emflaza is likely to produce equivalent therapeutic results as other available corticosteroids (e.g., prednisone); therefore, Emflaza is not medically necessary for treatment of Duchenne muscular dystrophy

|       |                                                                                                                                                                                            |
|-------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Notes | All requests for authorization will be denied by OptumRx and must be submitted through the appeals process to the UnitedHealthcare Community Plan Pharmacy Appeals team for consideration. |
|-------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

## 2 . Revision History

| Date       | Notes                                        |
|------------|----------------------------------------------|
| 11/25/2024 | Updated GPIs and product list to add generic |

Empaveli



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-260194                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Guideline Name</b> | Empaveli                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Pennsylvania (ACUPA)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 7/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                       |                       |
|-----------------------|-----------------------|
| Product Name:Empaveli |                       |
| Approval Length       | 12 month(s)           |
| Therapy Stage         | Initial Authorization |

| Guideline Type | Prior Authorization                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                | <p><b>Approval Criteria</b></p> <p><b>1</b> - Submission of medical records (e.g., chart notes, laboratory values, etc.) documenting the diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) as confirmed by BOTH of the following:</p> <p><b>1.1</b> Flow cytometry analysis confirming presence of PNH clones</p> <p style="text-align: center;"><b>AND</b></p> <p><b>1.2</b> Laboratory results, signs, and/or symptoms attributed to PNH (e.g., abdominal pain, anemia, dyspnea, extreme fatigue, smooth muscle dystonia, unexplained/unusual thrombosis, hemolysis/hemoglobinuria, kidney disease, pulmonary hypertension, etc.)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - ONE of the following:</p> <p><b>2.1</b> Patient will not be prescribed Empaveli in combination with another complement inhibitor used for the treatment of PNH (e.g., Bkempv, Fabhalta, PiaSky, Soliris, Ultomiris)</p> <p style="text-align: center;"><b>OR</b></p> <p><b>2.2</b> Patient is currently receiving another complement inhibitor (e.g., Bkempv, Fabhalta, PiaSky, Soliris, Ultomiris) which will be discontinued and Empaveli will be initiated in accordance with the United States Food and Drug Administration approved labeling</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Prescribed by, or in consultation with, ONE of the following:</p> <ul style="list-style-type: none"> <li>• Hematologist</li> <li>• Oncologist</li> </ul> |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                     |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Empaveli                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                     |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | 12 month(s)         |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of positive clinical response to Empaveli therapy [e.g., increased or stabilization of hemoglobin levels, reduction in transfusions, improvement in hemolysis, decrease in LDH (lactate dehydrogenase), increased reticulocyte count, etc.]</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Patient is not receiving Empaveli in combination with another complement inhibitor used for the treatment of paroxysmal nocturnal hemoglobinuria (PNH) (e.g., Bkemv, Fabhalta, PiaSky, Soliris, Ultomiris)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Prescribed by, or in consultation with, ONE of the following:</p> <ul style="list-style-type: none"> <li>• Hematologist</li> <li>• Oncologist</li> </ul> |                     |

## 2 . Revision History

| Date      | Notes                              |
|-----------|------------------------------------|
| 5/13/2025 | Updated formularies to add PA CAID |

Enbrel



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-180212                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Guideline Name</b> | Enbrel                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 4/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                     |                           |
|---------------------|---------------------------|
| Product Name:Enbrel |                           |
| Diagnosis           | Rheumatoid Arthritis (RA) |
| Approval Length     | 12 month(s)               |
| Therapy Stage       | Initial Authorization     |
| Guideline Type      | Prior Authorization       |

## **Approval Criteria**

**1** - All of the following:

**1.1** Diagnosis of moderately to severely active rheumatoid arthritis (RA)

**AND**

**1.2** ONE of the following:

**1.2.1** Failure to a 3 month trial of ONE non-biologic disease modifying anti-rheumatic drug (DMARD) [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine] at maximally indicated doses, confirmed by claims history or submission of medical records

**OR**

**1.2.2** History of intolerance or contraindication to one non-biologic DMARD [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine] (please specify intolerance or contraindication)

**OR**

**1.2.3** Patient has been previously treated with a targeted immunomodulator FDA (Food and Drug Administration)-approved for the treatment of rheumatoid arthritis confirmed by claims history or submission of medical records [e.g., Cimzia (certolizumab), adalimumab, Simponi (golimumab), Olumiant (baricitinib), Rinvoq (upadacitinib), Xeljanz/Xeljanz XR (tofacitinib)]

**AND**

**1.3** Patient is NOT receiving Enbrel in combination with another targeted immunomodulator [e.g., Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

**AND**

**1.4** Prescribed by or in consultation with a rheumatologist



**OR**

**2** - All of the following:

**2.1** Patient is currently on Enbrel therapy as confirmed by claims history or submission of medical records

**AND**

**2.2** Diagnosis of moderately to severely active rheumatoid arthritis

**AND**

**2.3** Patient is NOT receiving Enbrel in combination with another targeted immunomodulator [e.g., Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

**AND**

**2.4** Prescribed by or in consultation with a rheumatologist

|                                                                                                                               |                                                    |
|-------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------|
| Product Name:Enbrel                                                                                                           |                                                    |
| Diagnosis                                                                                                                     | Polyarticular Juvenile Idiopathic Arthritis (PJIA) |
| Approval Length                                                                                                               | 12 month(s)                                        |
| Therapy Stage                                                                                                                 | Initial Authorization                              |
| Guideline Type                                                                                                                | Prior Authorization                                |
| <b>Approval Criteria</b><br><b>1</b> - Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis |                                                    |

**AND**

**2** - Patient is NOT receiving Enbrel in combination with another targeted immunomodulator [e.g., Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

**AND**

**3** - Prescribed by or in consultation with a rheumatologist

|                     |                       |
|---------------------|-----------------------|
| Product Name:Enbrel |                       |
| Diagnosis           | Psoriatic Arthritis   |
| Approval Length     | 12 month(s)           |
| Therapy Stage       | Initial Authorization |
| Guideline Type      | Prior Authorization   |

**Approval Criteria**

**1** - All of the following:

**1.1** Diagnosis of active psoriatic arthritis

**AND**

**1.2** ONE of the following:

**1.2.1** Failure to a 3 month trial of methotrexate at the maximally indicated dose confirmed by claims history or submission of medical records

**OR**

**1.2.2** History of intolerance or contraindication to methotrexate (please specify intolerance or contraindication)

**OR**

**1.2.3** Patient has been previously treated with a targeted immunomodulator FDA (Food and Drug Administration)-approved for the treatment of psoriatic arthritis as confirmed by claims history or submission of medical records [e.g., Cimzia (certolizumab), adalimumab, Simponi (golimumab), ustekinumab, Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), Otezla (apremilast), Skyrizi (risankizumab-rzaa)]

**AND**

**1.3** Patient is NOT receiving Enbrel in combination with another targeted immunomodulator [e.g., Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

**AND**

**1.4** Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Dermatologist

**OR**

**2** - All of the following:

**2.1** Patient is currently on Enbrel therapy as confirmed by claims history or submission of medical records

**AND**

**2.2** Diagnosis of active psoriatic arthritis

**AND**

**2.3** Patient is NOT receiving Enbrel in combination with another targeted immunomodulator [e.g., Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

**AND**

**2.4** Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Dermatologist

|                                                                                                                                                                                                                                                                                                                                                                                                                                   |                       |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Enbrel                                                                                                                                                                                                                                                                                                                                                                                                               |                       |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                         | Plaque Psoriasis      |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                   | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                     | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                    | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - All of the following:</p> <p><b>1.1</b> Diagnosis of moderate to severe chronic plaque psoriasis</p> <p><b>AND</b></p> <p><b>1.2</b> ONE of the following:</p> <p><b>1.2.1</b> ALL of the following:</p> <p><b>1.2.1.1</b> Greater than or equal to 3% body surface area involvement, palmoplantar, facial, or genital involvement, or severe scalp psoriasis</p> <p><b>AND</b></p> |                       |

**1.2.1.2 ONE of the following:**

**1.2.1.2.1** Failure to one of the following topical therapy classes confirmed by claims history or submission of medical records:

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin
- Coal tar

**OR**

**1.2.1.2.2** History of intolerance or contraindication to all of the following topical therapy classes (please specify intolerance or contraindication)

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin
- Coal tar

**AND**

**1.2.1.3 ONE of the following:**

**1.2.1.3.1** Failure to a 3 month trial of methotrexate at the maximally indicated dose confirmed by claims history or submission of medical records

**OR**

**1.2.1.3.2** History of intolerance or contraindication to methotrexate (please specify intolerance or contraindication)

**OR**

**1.2.2** Patient has been previously treated with a targeted immunomodulator FDA (Food and Drug Administration)-approved for the treatment of plaque psoriasis as confirmed by claims

history or submission of medical records [e.g., Cimzia (certolizumab), adalimumab, Otezla (apremilast), Skyrizi (risankizumab-rzaa), ustekinumab, Tremfya (guselkumab)]

**AND**

**1.3** Patient is NOT receiving Enbrel in combination with another targeted immunomodulator [e.g., Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

**AND**

**1.4** Prescribed by or in consultation with a dermatologist

**OR**

**2** - All of the following:

**2.1** Patient is currently on Enbrel therapy as confirmed by claims history or submission of medical records

**AND**

**2.2** Diagnosis of moderate to severe chronic plaque psoriasis

**AND**

**2.3** Patient is NOT receiving Enbrel in combination with another targeted immunomodulator [e.g., Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

**AND**

**2.4** Prescribed by or in consultation with a dermatologist

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                        |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|
| Product Name:Enbrel                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                        |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Ankylosing Spondylitis |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 12 month(s)            |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Initial Authorization  |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Prior Authorization    |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - All of the following:</p> <p><b>1.1</b> Diagnosis of active ankylosing spondylitis</p> <p style="text-align: center;"><b>AND</b></p> <p><b>1.2</b> ONE of the following:</p> <p><b>1.2.1</b> Failure to two non-steroidal anti-inflammatory drugs (NSAIDs: e.g., ibuprofen, naproxen) at maximally indicated doses, each used for at least 4 weeks confirmed by claims history or submission of medical records</p> <p style="text-align: center;"><b>OR</b></p> <p><b>1.2.2</b> History of intolerance or contraindication to two NSAIDs (e.g., ibuprofen, naproxen) (please specify intolerance or contraindication)</p> <p style="text-align: center;"><b>OR</b></p> <p><b>1.2.3</b> Patient has been previously treated with a targeted immunomodulator FDA (Food and Drug Administration)-approved for the treatment of ankylosing spondylitis as confirmed by claims history or submission of medical records [e.g., adalimumab, Simponi (golimumab)]</p> <p style="text-align: center;"><b>AND</b></p> <p><b>1.3</b> Patient is NOT receiving Enbrel in combination with another targeted immunomodulator</p> |                        |

[e.g., Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

**AND**

**1.4** Prescribed by or in consultation with a rheumatologist

**OR**

**2** - All of the following:

**2.1** Patient is currently on Enbrel therapy as confirmed by claims history or submission of medical records

**AND**

**2.2** Diagnosis of active ankylosing spondylitis

**AND**

**2.3** Patient is NOT receiving Enbrel in combination with another targeted immunomodulator [e.g., Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

**AND**

**2.4** Prescribed by or in consultation with a rheumatologist

| Product Name:Enbrel |                                                                                                                                              |
|---------------------|----------------------------------------------------------------------------------------------------------------------------------------------|
| Diagnosis           | Rheumatoid Arthritis (RA), Polyarticular Juvenile Idiopathic Arthritis (PJIA), Plaque Psoriasis, Ankylosing Spondylitis, Psoriatic Arthritis |
| Approval Length     | 12 month(s)                                                                                                                                  |
| Therapy Stage       | Reauthorization                                                                                                                              |
| Guideline Type      | Prior Authorization                                                                                                                          |



### Approval Criteria

1 - Documentation of positive clinical response to Enbrel therapy

**AND**

2 - Patient is NOT receiving Enbrel in combination with another targeted immunomodulator [e.g., Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]\*

|       |                                                                                |
|-------|--------------------------------------------------------------------------------|
| Notes | * Examples of drug(s) may not be applicable based on the requested indication. |
|-------|--------------------------------------------------------------------------------|

## 2 . Revision History

| Date      | Notes                                                             |
|-----------|-------------------------------------------------------------------|
| 2/20/2025 | Updated formularies. Replaced Stelara with ustekinumab throughout |

Endari



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-228229                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Guideline Name</b> | Endari                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 5/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                                                           |                       |
|-----------------------------------------------------------|-----------------------|
| Product Name: Brand Endari, generic l-glutamine powd pack |                       |
| Diagnosis                                                 | Sickle cell disease   |
| Approval Length                                           | 12 month(s)           |
| Therapy Stage                                             | Initial Authorization |
| Guideline Type                                            | Prior Authorization   |

### Approval Criteria

1 - BOTH of the following:

- Diagnosis of sickle cell disease
- Used to reduce acute complications of sickle cell disease

**AND**

2 - ONE of the following:

- Patient is using Endari with concurrent hydroxyurea therapy
- Patient is unable to take hydroxyurea due to a contraindication or intolerance (please specify contraindication or intolerance)

**AND**

3 - Patient has had 2 or more painful sickle cell crises within the past 12 months

|                                                                                               |                     |
|-----------------------------------------------------------------------------------------------|---------------------|
| Product Name: Brand Endari, generic l-glutamine powder pack                                   |                     |
| Diagnosis                                                                                     | Sickle cell disease |
| Approval Length                                                                               | 12 month(s)         |
| Therapy Stage                                                                                 | Reauthorization     |
| Guideline Type                                                                                | Prior Authorization |
| <b>Approval Criteria</b><br>1 - Documentation of positive clinical response to Endari therapy |                     |

## 2 . Revision History

| Date | Notes |
|------|-------|
|------|-------|

|           |                                                                                                                                                                |
|-----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 3/27/2025 | Combined formularies. Added generic l-glutamine powd pack as a target. Updated product name lists and GPI tables accordingly. No changes to clinical criteria. |
|-----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------|

Ensacove



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-375187                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Guideline Name</b> | Ensacove                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 9/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                       |                                    |
|-----------------------|------------------------------------|
| Product Name:Ensacove |                                    |
| Diagnosis             | Non-small cell lung cancer (NSCLC) |
| Approval Length       | 12 month(s)                        |
| Therapy Stage         | Initial Authorization              |

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Prior Authorization |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1 - Diagnosis of non-small cell lung cancer (NSCLC)</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>2 - Tumor is anaplastic lymphoma kinase (ALK)-positive</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>3 - Disease is ONE of the following:</b></p> <ul style="list-style-type: none"> <li>• Advanced</li> <li>• Metastatic</li> <li>• Recurrent</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>4 - One of the following:</b></p> <p><b>4.1 Patient has not previously received an ALK-inhibitor [e.g., Alecensa (alectinib), Alunbrig (brigatinib), Lorbrena (lorlatinib), Xalkori (crizotinib), Zykadia (ceritinib)]</b></p> <p style="text-align: center;"><b>OR</b></p> <p><b>4.2 Patient is intolerant to or experiences disease progression on Xalkori (crizotinib)</b></p> |                     |

|                        |                                    |
|------------------------|------------------------------------|
| Product Name: Ensacove |                                    |
| Diagnosis              | Non-small cell lung cancer (NSCLC) |
| Approval Length        | 12 month(s)                        |
| Therapy Stage          | Reauthorization                    |
| Guideline Type         | Prior Authorization                |

**Approval Criteria**

1 - Patient does not show evidence of progressive disease while on Ensacove therapy

Product Name:Ensacove

|           |                           |
|-----------|---------------------------|
| Diagnosis | NCCN Recommended Regimens |
|-----------|---------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Ensacove

|           |                           |
|-----------|---------------------------|
| Diagnosis | NCCN Recommended Regimens |
|-----------|---------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                 |
|---------------|-----------------|
| Therapy Stage | Reauthorization |
|---------------|-----------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

1 - Documentation of positive clinical response to Ensacove therapy

## 2 . Revision History

|      |       |
|------|-------|
| Date | Notes |
|------|-------|

|           |                                                                                                                                    |
|-----------|------------------------------------------------------------------------------------------------------------------------------------|
| 8/19/2025 | Removed AZ from formularies - see AZ state specific Oral Oncology Agents GL-363219 for Ensacove. No clinical changes to guideline. |
|-----------|------------------------------------------------------------------------------------------------------------------------------------|



Enspryng



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-160434                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Guideline Name</b> | Enspryng                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 1/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                       |                       |
|-----------------------|-----------------------|
| Product Name:Enspryng |                       |
| Approval Length       | 12 month(s)           |
| Therapy Stage         | Initial Authorization |
| Guideline Type        | Prior Authorization   |
|                       |                       |

### **Approval Criteria**

**1** - Diagnosis of neuromyelitis optica spectrum disorder (NMOSD)

**AND**

**2** - Patient has a positive serologic test for anti-aquaporin-4 (AQP4) antibodies

**AND**

**3** - History of failure, contraindication, or intolerance to rituximab therapy

**AND**

**4** - One of the following:

- History of one or more relapses that required rescue therapy during the previous 12 months
- History of two or more relapses that required rescue therapy during the previous 24 months

**AND**

**5** - Prescribed by, or in consultation with, a neurologist

**AND**

**6** - Patient is NOT receiving Enspr yng in combination with any of the following:

- Disease modifying therapies for the treatment of multiple sclerosis [e.g., Gilenya (fingolimod), Tecfidera (dimethyl fumarate), Ocrevus (ocrelizumab), etc.]
- Complement inhibitors [e.g., Soliris (eculizumab), Ultomiris (ravulizumab), etc]
- Anti-IL6 (anti-interleukin-6) therapy [e.g., Actemra (tocilizumab)]
- B-cell depletion therapy [e.g., rituximab, Uplizna (inebilizumab)]

Product Name:Enspr yng

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                     |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | 12 month(s)         |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of positive clinical response to Enspryng therapy</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Prescribed by, or in consultation with, a neurologist</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Patient is NOT receiving Enspryng in combination with any of the following:</p> <ul style="list-style-type: none"> <li>• Disease modifying therapies for the treatment of multiple sclerosis [e.g., Gilenya (fingolimod), Tecfidera (dimethyl fumarate), Ocrevus (ocrelizumab), etc.]</li> <li>• Complement inhibitors [e.g., Soliris (eculizumab), Ultomiris (ravulizumab), etc]</li> <li>• Anti-IL6 (anti-interleukin-6) therapy [e.g., Actemra (tocilizumab)]</li> <li>• B-cell depletion therapy [e.g., rituximab, Uplizna (inebilizumab)]</li> </ul> |                     |

## 2 . Revision History

| Date       | Notes                                     |
|------------|-------------------------------------------|
| 11/11/2024 | Updated examples of complement inhibitors |

Entocort



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-216282                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Guideline Name</b> | Entocort                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 5/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                              |                     |
|------------------------------|---------------------|
| Product Name:budesonide caps |                     |
| Diagnosis                    | Crohn's Disease     |
| Approval Length              | 12 month(s)         |
| Guideline Type               | Prior Authorization |

**Approval Criteria**

1 - Used for the treatment of Crohn's disease

**2 . Revision History**

| Date      | Notes                                                  |
|-----------|--------------------------------------------------------|
| 3/18/2025 | Combined formularies. No changes to clinical criteria. |

Entresto



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-158342                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Guideline Name</b> | Entresto                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 12/1/2024 |
|-----------------|-----------|

## 1 . Criteria

|                                           |                       |
|-------------------------------------------|-----------------------|
| Product Name:Entresto, Entresto Sprinkles |                       |
| Approval Length                           | 12 month(s)           |
| Therapy Stage                             | Initial Authorization |
| Guideline Type                            | Prior Authorization   |
| Approval Criteria                         |                       |

**1** - Request is for continuation of therapy initiated during an inpatient stay

**OR**

**2** - ALL of the following:

**2.1** Diagnosis of pediatric heart failure with systemic left ventricular systolic dysfunction which is symptomatic

**AND**

**2.2** Prescribed by or in consultation with a cardiologist

**AND**

**2.3** If the request is for Entresto Sprinkles, the prescriber has given a clinical reason or special circumstance why the patient is unable to use regular Entresto tablets

**OR**

**3** - ALL of the following:

**3.1** Diagnosis of heart failure (with or without hypertension)

**AND**

**3.2** ONE of the following:

**3.2.1** Ejection fraction is less than or equal to 40 percent

**OR**

**3.2.2** BOTH of the following:

**3.2.2.1** Ejection fraction is greater than 40 percent

**AND**

**3.2.2.2** Patient has structural heart disease [i.e., left atrial enlargement (LAE) or left ventricular hypertrophy (LVH)]

**AND**

**3.3** Heart failure is classified as ONE of the following:

- New York Heart Association Class II
- New York Heart Association Class III
- New York Heart Association Class IV

**AND**

**3.4** Patient does not have a history of angioedema

**AND**

**3.5** Patient will discontinue any use of concomitant ACE (angiotensin converting enzyme) Inhibitor or ARB (angiotensin II receptor blocker) before initiating treatment with Entresto\*

**AND**

**3.6** Patient is not concomitantly on aliskiren therapy

**AND**

**3.7** Entresto is prescribed by, or in consultation with, a cardiologist

|       |                                                                                         |
|-------|-----------------------------------------------------------------------------------------|
| Notes | *ACE inhibitors must be discontinued at least 36 hours prior to initiation of Entresto. |
|-------|-----------------------------------------------------------------------------------------|

Product Name:Entresto, Entresto Sprinkles



|                                                                                                                                                                                                                                                                                                                                                                      |                     |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Approval Length                                                                                                                                                                                                                                                                                                                                                      | 12 month(s)         |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                        | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                       | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - The Entresto dose has been titrated to a dose of 97 mg (milligrams)/103 mg twice daily or the maximum labeled dose for pediatric patients, or to a maximum dose as tolerated by the patient</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Documentation of positive clinical response to therapy</p> |                     |

## 2 . Revision History

| Date       | Notes                                     |
|------------|-------------------------------------------|
| 10/31/2024 | Updated formularies. No clinical changes. |

Entyvio SC



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-180216                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Guideline Name</b> | Entyvio SC                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 4/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                         |                         |
|-------------------------|-------------------------|
| Product Name:Entyvio SC |                         |
| Diagnosis               | Ulcerative Colitis (UC) |
| Approval Length         | 12 month(s)             |
| Therapy Stage           | Initial Authorization   |
| Guideline Type          | Prior Authorization     |

**Approval Criteria**

**1** - Submission of medical records documenting clinical rationale for need of subcutaneous Entyvio in place of Entyvio administered intravenously (covered under the medical benefit)

**AND**

**2** - Diagnosis of moderately to severely active ulcerative colitis (UC)

**AND**

**3** - ONE of the following:

**3.1** Patient has been established on therapy with Entyvio under an active UnitedHealthcare medical benefit prior authorization for the treatment of moderately to severely active ulcerative colitis

**OR**

**3.2** Patient is currently on Entyvio for subcutaneous use therapy as confirmed by claims history or submission of medical records

**AND**

**4** - Patient is NOT receiving Entyvio for subcutaneous use in combination with another targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), ustekinumab, Xeljanz (tofacitinib)]

**AND**

**5** - Prescribed by or in consultation with a gastroenterologist

Product Name:Entyvio SC

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                       |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Crohn's disease (CD)  |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Submission of medical records documenting clinical rationale for need of subcutaneous Entyvio in place of Entyvio administered intravenously (covered under the medical benefit)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Diagnosis of moderately to severely active Crohn's disease (CD)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - ONE of the following:</p> <p><b>3.1</b> Patient has been established on therapy with Entyvio under an active UnitedHealthcare medical benefit prior authorization for the treatment of moderately to severely active Crohn's disease</p> <p style="text-align: center;"><b>OR</b></p> <p><b>3.2</b> Patient is currently on Entyvio for subcutaneous use therapy as confirmed by claims history or submission of medical records</p> <p style="text-align: center;"><b>AND</b></p> <p><b>4</b> - Patient is NOT receiving Entyvio in combination with a targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), ustekinumab, Xeljanz (tofacitinib)]</p> <p style="text-align: center;"><b>AND</b></p> |                       |

**5** - Prescribed by or in consultation with a gastroenterologist

**Product Name:**Entyvio SC

|           |                                               |
|-----------|-----------------------------------------------|
| Diagnosis | Ulcerative Colitis (UC), Crohn's disease (CD) |
|-----------|-----------------------------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                 |
|---------------|-----------------|
| Therapy Stage | Reauthorization |
|---------------|-----------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

### Approval Criteria

**1** - Documentation of positive clinical response to Entyvio for subcutaneous use therapy

**AND**

**2** - Patient is not receiving Entyvio in combination with a targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), ustekinumab, Xeljanz (tofacitinib)]

## 2 . Revision History

| Date      | Notes                                                                                                                |
|-----------|----------------------------------------------------------------------------------------------------------------------|
| 2/20/2025 | Updated formularies. Replaced Stelara with ustekinumab throughout program. Updated bypass language for current users |

Eohilia



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-317188                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Guideline Name</b> | Eohilia                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Washington (ACUWA, ACUWAAHE, ACUWAC)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 8/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                      |                       |
|----------------------|-----------------------|
| Product Name:Eohilia |                       |
| Approval Length      | 12 month(s)           |
| Therapy Stage        | Initial Authorization |

| Guideline Type | Prior Authorization                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                | <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of eosinophilic esophagitis (EoE)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Patient is experiencing symptoms related to esophageal dysfunction (e.g., dysphagia, food impaction, chest pain that is often centrally located and may not respond to antacids, gastroesophageal reflux disease-like symptoms/refractory heartburn, upper abdominal pain)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Submission of medical records (e.g., chart notes, laboratory values, etc.) documenting eosinophil-predominant inflammation on esophageal biopsy, consisting of a peak value of <math>\geq 15</math> intraepithelial eosinophils per high power field (HPF)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>4</b> - Secondary causes of esophageal eosinophilia have been ruled out</p> <p style="text-align: center;"><b>AND</b></p> <p><b>5</b> - ONE of the following:</p> <p><b>5.1</b> History of suboptimal response to an 8 week trial of BOTH of the following as confirmed by claims history or submission of medical records:</p> <ul style="list-style-type: none"> <li>• Proton pump inhibitor (e.g., pantoprazole, omeprazole)</li> <li>• Inhalational corticosteroid administered orally [e.g., budesonide inhalation suspension (generic Pulmicort Respules), Fluticasone HFA (Flovent HFA authorized generic)]</li> </ul> <p style="text-align: center;"><b>OR</b></p> |

**5.2** History of contraindication or intolerance to BOTH of the following (please specify intolerance or contraindication):

- Proton pump inhibitor (e.g., pantoprazole, omeprazole)
- Inhalational corticosteroid administered orally [e.g., budesonide inhalation suspension (generic Pulmicort Respules), Fluticasone HFA (Flovent HFA authorized generic)]

**AND**

**6** - Prescribed by or in consultation with ONE of the following:

- Allergist/Immunologist
- Gastroenterologist

|                                                                                                                                                                                                        |                     |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Eohilia                                                                                                                                                                                   |                     |
| Approval Length                                                                                                                                                                                        | 12 month(s)         |
| Therapy Stage                                                                                                                                                                                          | Reauthorization     |
| Guideline Type                                                                                                                                                                                         | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of positive clinical response to Eohilia therapy as evidenced by a reduction in intraepithelial eosinophils per high power field (HPF)</p> |                     |

## 2 . Revision History

| Date     | Notes                                                                                                                                                                         |
|----------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 7/2/2025 | Combined formularies. Added reauth criteria section. For initial auth, updated approval duration and updated failure language to suboptimal response. Minor cosmetic updates. |



Erivedge



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-117353                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Guideline Name</b> | Erivedge                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 1/1/2023 |
|-----------------|----------|

## 1 . Criteria

|                       |                       |
|-----------------------|-----------------------|
| Product Name:Erivedge |                       |
| Diagnosis             | Basal Cell Carcinoma  |
| Approval Length       | 12 month(s)           |
| Therapy Stage         | Initial Authorization |
| Guideline Type        | Prior Authorization   |

**Approval Criteria**

1 - Diagnosis of metastatic basal cell carcinoma

**OR**

2 - BOTH of the following:

2.1 Diagnosis of locally advanced basal cell carcinoma

**AND**

2.2 ONE of the following:

- Cancer has recurred following surgery
- Patient is not a candidate for surgery
- Patient is not a candidate for radiation

|                                                                                                                                                                                      |                       |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Erivedge                                                                                                                                                                |                       |
| Diagnosis                                                                                                                                                                            | Medulloblastoma       |
| Approval Length                                                                                                                                                                      | 12 month(s)           |
| Therapy Stage                                                                                                                                                                        | Initial Authorization |
| Guideline Type                                                                                                                                                                       | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of medulloblastoma</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Patient has mutations in the sonic hedgehog pathway</p> |                       |

**AND**

**3** - Patient has failed prior chemotherapy

Product Name:Erivedge

|           |                                       |
|-----------|---------------------------------------|
| Diagnosis | Basal Cell Carcinoma, Medulloblastoma |
|-----------|---------------------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                 |
|---------------|-----------------|
| Therapy Stage | Reauthorization |
|---------------|-----------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

**1** - Patient does not show evidence of progressive disease while on Erivedge therapy

Product Name:Erivedge

|           |                           |
|-----------|---------------------------|
| Diagnosis | NCCN Recommended Regimens |
|-----------|---------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

**1** - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Erivedge

|           |                           |
|-----------|---------------------------|
| Diagnosis | NCCN Recommended Regimens |
|-----------|---------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                 |
|---------------|-----------------|
| Therapy Stage | Reauthorization |
|---------------|-----------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

1 - Documentation of positive clinical response to Erivedge therapy

**2 . Revision History**

| Date      | Notes                                     |
|-----------|-------------------------------------------|
| 12/1/2022 | Updated formularies, cleaned up criteria. |

Erleada



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-138262                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Guideline Name</b> | Erleada                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 2/1/2024 |
|-----------------|----------|

## 1 . Criteria

|                      |                       |
|----------------------|-----------------------|
| Product Name:Erleada |                       |
| Diagnosis            | Prostate Cancer       |
| Approval Length      | 12 month(s)           |
| Therapy Stage        | Initial Authorization |
| Guideline Type       | Prior Authorization   |

## Approval Criteria

**1** - Diagnosis of prostate cancer

**AND**

**2** - ONE of the following:

**2.1** BOTH of the following:

- Disease is castration-resistant or recurrent
- Disease is non-metastatic

**OR**

**2.2** BOTH of the following:

- Disease is castration-sensitive or naïve
- Disease is metastatic

**AND**

**3** - ONE of the following:

**3.1** Used in combination with a gonadotropin-releasing hormone (GnRH) analog [e.g., Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix)]

**OR**

**3.2** Patient has had bilateral orchiectomy

|                      |                 |
|----------------------|-----------------|
| Product Name:Erleada |                 |
| Diagnosis            | Prostate Cancer |
| Approval Length      | 12 month(s)     |
| Therapy Stage        | Reauthorization |

|                                                                                                                       |                     |
|-----------------------------------------------------------------------------------------------------------------------|---------------------|
| Guideline Type                                                                                                        | Prior Authorization |
| <b>Approval Criteria</b><br><b>1</b> - Patient does not show evidence of progressive disease while on Erleada therapy |                     |

|                                                                                                                                            |                          |
|--------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|
| Product Name:Erleada                                                                                                                       |                          |
| Diagnosis                                                                                                                                  | NCCN Recommended Regimen |
| Approval Length                                                                                                                            | 12 month(s)              |
| Therapy Stage                                                                                                                              | Initial Authorization    |
| Guideline Type                                                                                                                             | Prior Authorization      |
| <b>Approval Criteria</b><br><b>1</b> - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium |                          |

|                                                                                                       |                          |
|-------------------------------------------------------------------------------------------------------|--------------------------|
| Product Name:Erleada                                                                                  |                          |
| Diagnosis                                                                                             | NCCN Recommended Regimen |
| Approval Length                                                                                       | 12 month(s)              |
| Therapy Stage                                                                                         | Reauthorization          |
| Guideline Type                                                                                        | Prior Authorization      |
| <b>Approval Criteria</b><br><b>1</b> - Documentation of positive clinical response to Erleada therapy |                          |

## 2 . Revision History

|      |       |
|------|-------|
| Date | Notes |
|------|-------|

|            |                   |
|------------|-------------------|
| 12/28/2023 | Updated GPI list. |
|------------|-------------------|



Erythropoietic Agents



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-238236                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Guideline Name</b> | Erythropoietic Agents                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 6/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                                                  |                                            |
|--------------------------------------------------|--------------------------------------------|
| Product Name: Aranesp, Epogen, Procrit, Retacrit |                                            |
| Diagnosis                                        | Anemia Due to Chronic Kidney Disease (CKD) |
| Approval Length                                  | 12 month(s)                                |
| Therapy Stage                                    | Initial Authorization                      |
| Guideline Type                                   | Prior Authorization                        |

**Approval Criteria**

**1** - Diagnosis of chronic kidney disease (CKD)

**AND**

**2** - Hematocrit is less than 30 percent at initiation of therapy

**AND**

**3** - Patient does not have evidence of other causes of anemia (e.g., iron deficiency, hemolysis, vitamin B12 deficiency)

**AND**

**4** - ONE of the following:

**4.1** Patient is on dialysis

**OR**

**4.2** ALL of the following:

**4.2.1** Patient is NOT on dialysis

**AND**

**4.2.2** The rate of hematocrit decline indicates the likelihood of requiring a red blood cell (RBC) transfusion

**AND**

**4.2.3** Therapeutic goal is reducing the risk of alloimmunization and/or other RBC transfusion-related risks

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                            |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|
| Product Name:Aranesp, Epogen, Procrit, Retacrit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                            |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Anemia Due to Chronic Kidney Disease (CKD) |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 12 month(s)                                |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Reauthorization                            |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Prior Authorization                        |
| <p><b>Approval Criteria</b></p> <p>1 - Documentation of positive clinical response to erythropoietin stimulating agent (ESA) therapy</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - ONE of the following:</p> <p>2.1 BOTH of the following:</p> <p>2.1.1 Patient is on dialysis</p> <p style="text-align: center;"><b>AND</b></p> <p>2.1.2 Hematocrit remains less than 33 percent</p> <p style="text-align: center;"><b>OR</b></p> <p>2.2 ALL of the following:</p> <p>2.2.1 Patient is NOT on dialysis</p> <p style="text-align: center;"><b>AND</b></p> <p>2.2.2 Hematocrit remains less than 30 percent</p> |                                            |

**AND**

**2.2.3** Therapeutic goal is reducing the risk of alloimmunization and/or other RBC transfusion

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                      |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------|
| Product Name:Epogen, Procrit, Retacrit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                      |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Anemia Associated with Zidovudine Treatment in HIV-Infected Patients |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | 12 month(s)                                                          |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Initial Authorization                                                |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Prior Authorization                                                  |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Patient is receiving zidovudine administered at less than or equal to 4200 milligrams per week</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Endogenous serum erythropoietin level is less than or equal to 500 milliunits per milliliter</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Hematocrit is less than 30 percent at initiation of therapy</p> <p style="text-align: center;"><b>AND</b></p> <p><b>4</b> - Patient does not have evidence of other causes of anemia (e.g., iron deficiency, hemolysis, vitamin B12 deficiency)</p> |                                                                      |

|                                        |                                                                      |
|----------------------------------------|----------------------------------------------------------------------|
| Product Name:Epogen, Procrit, Retacrit |                                                                      |
| Diagnosis                              | Anemia Associated with Zidovudine Treatment in HIV-Infected Patients |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                     |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 12 month(s)         |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of positive clinical response to erythropoietin stimulating agent (ESA) therapy</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Patient is receiving zidovudine administered at less than or equal to 4200 milligrams per week</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Endogenous serum erythropoietin level less than or equal to 500 milliunits per milliliter</p> <p style="text-align: center;"><b>AND</b></p> <p><b>4</b> - Hematocrit remains less than or equal to 36 percent for continuation of therapy</p> |                     |

|                                                                                                                        |                                   |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------|
| Product Name: Aranesp, Epogen, Procrit, Retacrit                                                                       |                                   |
| Diagnosis                                                                                                              | Anemia Due to Cancer Chemotherapy |
| Approval Length                                                                                                        | 12 month(s)                       |
| Therapy Stage                                                                                                          | Initial Authorization             |
| Guideline Type                                                                                                         | Prior Authorization               |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Hematocrit less than or equal to 30 percent at initiation of therapy</p> |                                   |

**AND**

**2** - Patient does not have evidence of other causes of anemia (e.g., iron deficiency, hemolysis, vitamin B12 deficiency) and there is documentation of normal iron stores

**AND**

**3** - One of the following:

**3.1** Patient has moderate to severe chronic kidney disease (CKD)

**OR**

**3.2** Undergoing palliative treatment

**OR**

**3.3** Receiving myelosuppressive chemotherapy not given with curative intent

**OR**

**3.4** Both of the following:

- Receiving myelosuppressive chemotherapy with curative intent
- Patient is refusing blood transfusion(s)

|                                                  |                                   |
|--------------------------------------------------|-----------------------------------|
| Product Name: Aranesp, Epogen, Procrit, Retacrit |                                   |
| Diagnosis                                        | Anemia Due to Cancer Chemotherapy |
| Approval Length                                  | 12 month(s)                       |
| Therapy Stage                                    | Reauthorization                   |
| Guideline Type                                   | Prior Authorization               |

**Approval Criteria**

1 - Documentation of positive clinical response to erythropoietin stimulating agent (ESA) therapy

**AND**

2 - Chemotherapy is given as palliative treatment

**AND**

3 - Hematocrit remains less than 30 percent for continuation of therapy

Product Name: Epogen, Procrit, Retacrit

|           |                                                                                     |
|-----------|-------------------------------------------------------------------------------------|
| Diagnosis | Preoperative Use for Reduction of Allogeneic Blood Transfusions in Surgery Patients |
|-----------|-------------------------------------------------------------------------------------|

|                 |            |
|-----------------|------------|
| Approval Length | 3 month(s) |
|-----------------|------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

1 - Perioperative hematocrit is greater than 30 percent and less than or equal to 39 percent

**AND**

2 - Patient is expected to require at least 2 units of blood during the surgical procedure

**AND**

3 - Patient is at high risk for blood loss during surgery

**AND**

**4** - Patient is unable or unwilling to donate autologous blood

**AND**

**5** - Surgery procedure is elective, non-cardiac, and non-vascular

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                 |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|
| Product Name: Aranesp, Epogen, Procrit, Retacrit                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                 |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Anemia Associated with Myelodysplastic Syndrome |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 12 month(s)                                     |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Initial Authorization                           |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Prior Authorization                             |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of myelodysplastic syndrome (MDS)</p> <p><b>AND</b></p> <p><b>2</b> - Serum erythropoietin level less than or equal to 500 milliunits per milliliter</p> <p><b>AND</b></p> <p><b>3</b> - Hematocrit is less than or equal to 30 percent at the initiation of therapy</p> <p><b>AND</b></p> <p><b>4</b> - Patient does not have evidence of other causes of anemia (e.g., iron deficiency, hemolysis, vitamin B12 deficiency)</p> |                                                 |



**AND**

**5** - Treatment of lower risk [defined as IPSS-R (Very Low, Low, Intermediate)] disease with symptomatic anemia

**AND**

**6** - One of the following:

**6.1** Patient is with del(5q) chromosomal abnormality

**OR**

**6.2** Both of the following:

- Patient is without del(5q) chromosomal abnormality
- Ring sideroblasts less than 15% (or ring sideroblasts less than 5% with an SF3B1 mutation)

**OR**

**6.3** All of the following:

- Patient is without del(5q) chromosomal abnormality
- Ring sideroblasts greater than or equal to 15% (or ring sideroblasts greater than or equal to 5% with an SF3B1 mutation)
- Following no response to Reblozyl (luspatercept-aamt)

|                                                     |                                                 |
|-----------------------------------------------------|-------------------------------------------------|
| Product Name: Aranesp, Epogen, Procrit, or Retacrit |                                                 |
| Diagnosis                                           | Anemia Associated with Myelodysplastic syndrome |
| Approval Length                                     | 12 month(s)                                     |
| Therapy Stage                                       | Reauthorization                                 |
| Guideline Type                                      | Prior Authorization                             |

**Approval Criteria**

**1** - Hematocrit remains less than or equal to 36 percent for continuation of therapy

**AND**

**2** - Documentation of positive clinical response to erythropoietin stimulating agent (ESA) therapy

**AND**

**3** - Serum erythropoietin level less than or equal to 500 milliunits per milliliter

|                                                                                                                                                                                                                                                                                                                                                                                          |                                                                     |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------|
| Product Name: Aranesp, Epogen, Procrit, Retacrit                                                                                                                                                                                                                                                                                                                                         |                                                                     |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                | Anemia associated with Myeloproliferative Neoplasms – Myelofibrosis |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                          | 12 month(s)                                                         |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                            | Initial Authorization                                               |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                           | Prior Authorization                                                 |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Serum erythropoietin level less than or equal to 500 mUnits/mL</p> <p><b>AND</b></p> <p><b>2</b> - Hematocrit is less than or equal to 30 percent at the initiation of therapy</p> <p><b>AND</b></p> <p><b>3</b> - Patient does not have evidence of other causes of anemia (e.g., iron deficiency, hemolysis, vitamin B12 deficiency)</p> |                                                                     |

|                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                     |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------|
| Product Name:Aranesp, Epogen, Procrit, Retacrit                                                                                                                                                                                                                                                                                                                                                           |                                                                     |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                 | Anemia associated with Myeloproliferative Neoplasms – Myelofibrosis |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                           | 12 month(s)                                                         |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                             | Reauthorization                                                     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                            | Prior Authorization                                                 |
| <p><b>Approval Criteria</b></p> <p>1 - Documentation of positive clinical response to erythropoietin stimulating agent (ESA) therapy</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Serum erythropoietin level less than or equal to 500 mUnits/mL</p> <p style="text-align: center;"><b>AND</b></p> <p>3 - Hematocrit remains less than or equal to 36 percent for continuation of therapy</p> |                                                                     |

|                                                                                           |                                                                           |
|-------------------------------------------------------------------------------------------|---------------------------------------------------------------------------|
| Product Name:Epogen, Procrit, Retacrit                                                    |                                                                           |
| Diagnosis                                                                                 | Anemia in Patients with Hepatitis C with Ribavirin and Interferon Therapy |
| Approval Length                                                                           | 12 month(s)                                                               |
| Therapy Stage                                                                             | Initial Authorization                                                     |
| Guideline Type                                                                            | Prior Authorization                                                       |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of hepatitis C virus (HCV) infection</p> |                                                                           |

**AND**

**2** - Patient is receiving ribavirin and interferon therapy

**AND**

**3** - Hematocrit is less than or equal to 30 percent at initiation of therapy

**AND**

**4** - Patient does not have evidence of other causes of anemia (e.g., iron deficiency, hemolysis, vitamin B12 deficiency)

|                                                                                                                                                                                                                                                                                    |                                                                           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------|
| Product Name:Epogen, Procrit, Retacrit                                                                                                                                                                                                                                             |                                                                           |
| Diagnosis                                                                                                                                                                                                                                                                          | Anemia in Patients with Hepatitis C with Ribavirin and Interferon Therapy |
| Approval Length                                                                                                                                                                                                                                                                    | 12 month(s)                                                               |
| Therapy Stage                                                                                                                                                                                                                                                                      | Reauthorization                                                           |
| Guideline Type                                                                                                                                                                                                                                                                     | Prior Authorization                                                       |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Hematocrit remains less than or equal to 36 percent for continuation of care</p> <p><b>AND</b></p> <p><b>2</b> - Documentation of positive clinical response to erythropoietin stimulating agent (ESA) therapy</p> <p><b>AND</b></p> |                                                                           |

**3** - Patient is receiving ribavirin and interferon therapy

**Product Name:** Aranesp, Epogen, Procrit, Retacrit

**Diagnosis** Erythropoietin Stimulating Agents -Off-Label Uses

**Guideline Type** Prior Authorization

**Approval Criteria**

**1** - Off-label requests will be evaluated on a case-by-case basis by a clinical pharmacist

**AND**

**2** - Requests for coverage in patients with hemoglobin (Hgb) greater than 10 grams per deciliter or hematocrit (Hct) greater than 30 percent will not be approved

## 2 . Revision History

| Date      | Notes               |
|-----------|---------------------|
| 4/16/2025 | Updated formularies |

Esbriet, Ofev



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-322188                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Guideline Name</b> | Esbriet, Ofev                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 8/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                                                        |                               |
|--------------------------------------------------------|-------------------------------|
| Product Name: Brand Esbriet, generic pirfenidone, Ofev |                               |
| Diagnosis                                              | Idiopathic Pulmonary Fibrosis |
| Approval Length                                        | 12 month(s)                   |
| Therapy Stage                                          | Initial Authorization         |

| Guideline Type | Prior Authorization                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                | <p><b>Approval Criteria</b></p> <p><b>1 - Diagnosis of idiopathic pulmonary fibrosis (IPF) as documented by ALL of the following:</b></p> <p><b>1.1</b> Exclusion of other known causes of interstitial lung disease (e.g., domestic and occupational environmental exposures, connective tissue disease, and drug toxicity), as documented by an ICD-10 Code of J84.112 (idiopathic pulmonary fibrosis)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>1.2 ONE</b> of the following:</p> <p><b>1.2.1</b> If the patient was NOT subjected to surgical lung biopsy, the presence of a usual interstitial pneumonia (UIP) pattern on high-resolution computed tomography (HRCT) revealing IPF or probable IPF</p> <p style="text-align: center;"><b>OR</b></p> <p><b>1.2.2</b> If the patient was subjected to a lung biopsy, both HRCT and surgical lung biopsy pattern reveal IPF or probable IPF</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2 - ONE</b> of the following:</p> <p><b>2.1</b> If the request is for Esbriet (pirfenidone), it is not being used in combination with Ofev</p> <p style="text-align: center;"><b>OR</b></p> <p><b>2.2</b> If the request is for Ofev, it is not being used in combination with Esbriet (pirfenidone)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3 - The prescriber is a pulmonologist</b></p> |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                               |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|
| Product Name: Brand Esbriet, generic pirfenidone, Ofev                                                                                                                                                                                                                                                                                                                                                                                                  |                               |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                               | Idiopathic Pulmonary Fibrosis |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                         | 12 month(s)                   |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                           | Reauthorization               |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                          | Prior Authorization           |
| <p><b>Approval Criteria</b></p> <p>1 - Documentation of positive clinical response to the requested therapy</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - ONE of the following:</p> <p>2.1 If the request is for Esbriet (pirfenidone), it is not being used in combination with Ofev</p> <p style="text-align: center;"><b>OR</b></p> <p>2.2 If the request is for Ofev, it is not being used in combination with Esbriet (pirfenidone)</p> |                               |

|                                                                                                                                                                                                   |                                                         |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------|
| Product Name: Ofev                                                                                                                                                                                |                                                         |
| Diagnosis                                                                                                                                                                                         | Systemic Sclerosis-Associated Interstitial Lung Disease |
| Approval Length                                                                                                                                                                                   | 12 month(s)                                             |
| Therapy Stage                                                                                                                                                                                     | Initial Authorization                                   |
| Guideline Type                                                                                                                                                                                    | Prior Authorization                                     |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD) as documented by ALL of the following:</p> <p>1.1 ONE of the following:</p> |                                                         |



**1.1.1** Skin thickening of the fingers of both hands extending proximal to the metacarpophalangeal joints

**OR**

**1.1.2** At least TWO of the following:

- Skin thickening of the fingers (e.g., puffy fingers, sclerodactyly of the fingers)
- Fingertip lesions (e.g., digital tip ulcers, fingertip pitting scars)
- Telangiectasia
- Abnormal nailfold capillaries
- Pulmonary arterial hypertension
- Raynaud's phenomenon
- SSc-related autoantibodies [e.g., anticentromere, anti-topoisomerase I, anti-RNA (ribonucleic acid) polymerase III]

**AND**

**1.2** Presence of interstitial lung disease as determined by finding evidence of pulmonary fibrosis on high-resolution computed tomography (HRCT), involving at least 10% of the lungs

**AND**

**2** - Ofev is not being used in combination with Esbriet (pirfenidone)

**AND**

**3** - The prescriber is a pulmonologist

|                   |                                                                          |
|-------------------|--------------------------------------------------------------------------|
| Product Name:Ofev |                                                                          |
| Diagnosis         | Chronic Fibrosing Interstitial Lung Disease with a Progressive Phenotype |
| Approval Length   | 12 month(s)                                                              |
| Therapy Stage     | Initial Authorization                                                    |
| Guideline Type    | Prior Authorization                                                      |

### Approval Criteria

**1** - Diagnosis of chronic fibrosing interstitial lung disease (ILD) with a progressive phenotype as documented by BOTH of the following:

**1.1** Presence of fibrotic ILD as determined by finding evidence of pulmonary fibrosis on HRCT (high-resolution computed tomography), involving at least 10% of the lungs

**AND**

**1.2** Patient is presenting with clinical signs of progression as defined by ONE of the following in the previous 24 months:

**1.2.1** Forced vital capacity (FVC) decline of greater than 10%

**OR**

**1.2.2** TWO of the following:

- FVC decline of greater than or equal to 5%, but less than 10%
- Patient is experiencing worsening respiratory symptoms
- Patient is exhibiting increasing extent of fibrotic changes on chest imaging

**AND**

**2** - Ofev is not being used in combination with Esbriet (pirfenidone)

**AND**

**3** - The prescriber is a pulmonologist

|                   |                                                                                                                                   |
|-------------------|-----------------------------------------------------------------------------------------------------------------------------------|
| Product Name:Ofev |                                                                                                                                   |
| Diagnosis         | Systemic Sclerosis-Associated Interstitial Lung Disease, Chronic Fibrosing Interstitial Lung Disease with a Progressive Phenotype |
| Approval Length   | 12 month(s)                                                                                                                       |

|                                                                                                                                                                                                                                  |                     |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Therapy Stage                                                                                                                                                                                                                    | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                   | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p>1 - Documentation of positive clinical response to Ofev therapy</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Ofev is not being used in combination with Esbriet (pirfenidone)</p> |                     |

## 2 . Revision History

| Date     | Notes                                                                      |
|----------|----------------------------------------------------------------------------|
| 7/7/2025 | Updated formularies. Removed prescriber check from reauthorization section |

Eucrisa



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-138360                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Guideline Name</b> | Eucrisa                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 2/1/2024 |
|-----------------|----------|

## 1 . Criteria

|                      |              |
|----------------------|--------------|
| Product Name:Eucrisa |              |
| Approval Length      | 12 month(s)  |
| Guideline Type       | Step Therapy |
| Approval Criteria    |              |

**1 - BOTH of the following:**

**1.1 ONE of the following:**

**1.1.1** Failure to ONE topical corticosteroid [e.g., mometasone furoate, fluocinolone acetonide (generic Synalar), fluocinonide] as confirmed by claims history or submission of medical records

**OR**

**1.1.2** History of contraindication or intolerance ONE topical corticosteroid [e.g., mometasone furoate, fluocinolone acetonide (generic Synalar), fluocinonide] (please specify contraindication or intolerance)

**AND**

**1.2 ONE of the following:**

**1.2.1** Patient is less than 2 years of age

**OR**

**1.2.2** Patient is greater than or equal to 2 years of age and ONE of the following:

- Failure to ONE topical calcineurin inhibitor [e.g., pimecrolimus (generic Elidel), tacrolimus (generic Protopic)] as confirmed by claims history or submission of medical records
- History of contraindication or intolerance to ONE topical calcineurin inhibitor [e.g., pimecrolimus (generic Elidel), tacrolimus (generic Protopic)] (Please specify contraindication or intolerance)

**OR**

**2 - Patient is currently on Eucrisa therapy as confirmed by claims history or submission of medical records**

## **2 . Revision History**

UnitedHealthcare Community Plan of New Jersey – Clinical Pharmacy Guidelines

| Date       | Notes                                                                                                     |
|------------|-----------------------------------------------------------------------------------------------------------|
| 12/29/2023 | Removed "Medicaid - Community & State Colorado (RMHCAID, RM HCHP, RMHWRP)" from benefit coverage section. |

Evrysdi



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-246201                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Guideline Name</b> | Evrysdi                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 7/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                      |                       |
|----------------------|-----------------------|
| Product Name:Evrysdi |                       |
| Approval Length      | 12 month(s)           |
| Therapy Stage        | Initial Authorization |
| Guideline Type       | Prior Authorization   |

### **Approval Criteria**

**1** - Diagnosis of spinal muscular atrophy (SMA)

**AND**

**2** - Submission of medical records (e.g., chart notes, laboratory values) confirming the mutation or deletion of genes in chromosome 5q resulting in ONE of the following:

- Homozygous gene deletion or mutation of SMN1 gene (e.g., homozygous deletion of exon 7 at locus 5q13)
- Compound heterozygous mutation of SMN1 gene [e.g., deletion of SMN1 exon 7 (allele 1) and mutation of SMN1 (allele 2)]

**AND**

**3** - Patient is not dependent on invasive ventilation

**AND**

**4** - Patient is not dependent on the use of non-invasive ventilation beyond use for naps and nighttime sleep

**AND**

**5** - Patient is not receiving concomitant chronic survival motor neuron (SMN)-modifying therapy [e.g., Spinraza (nusinersen)]

**AND**

**6** - One of the following:

**6.1** Patient has not previously received gene replacement therapy for the treatment of SMA [e.g., Zolgensma (onasemnogene abeparvovec-xioi)]



**OR**

**6.2 Both of the following:**

- Patient has previously received gene replacement therapy [e.g., Zolgensma (onasemnogene abeparvovec-xioi)] for the treatment of SMA
- Submission of medical records (e.g., chart notes, laboratory values) documenting a clinically meaningful functional decline (e.g., loss of motor milestone) since receiving gene replacement therapy [e.g., Zolgensma (onasemnogene abeparvovec-xioi)]

**AND**

**7 -** Submission of medical records (e.g., chart notes, laboratory values) documenting the baseline assessment of at least ONE of the following exams (based on patient age and motor ability) to establish baseline motor ability (baseline motor function analysis could include assessments evaluated prior to receipt of previous chronic SMN-modifying therapy if transitioning therapy)\*:

- Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND)
- Hammersmith Infant Neurological Exam Part 2 (HINE-2)
- Hammersmith Functional Motor Scale Expanded (HFMSE)
- Revised Upper Limb Module (RULM) Test
- Motor Function Measure 32 (MFM-32) Scale

**AND**

**8 -** Prescribed by or in consultation with a neurologist with expertise in the treatment of SMA

|       |                                                                                                                                                                                                                                                                                                      |
|-------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Notes | *Baseline assessments for patients less than 2 months of age requesting Evrysdi are not necessary in order not to delay access to initial therapy in recently diagnosed infants. Initial assessments shortly post-therapy can serve as baseline with respect to efficacy reauthorization assessment. |
|-------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                      |                     |
|----------------------|---------------------|
| Product Name:Evrysdi |                     |
| Approval Length      | 12 month(s)         |
| Therapy Stage        | Reauthorization     |
| Guideline Type       | Prior Authorization |

## **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes, laboratory values) with the most recent results documenting a positive clinical response to Evrysdi compared to pretreatment baseline status [inclusive of baseline assessments prior to receipt of previous chronic survival motor neuron (SMN)-modifying therapy] as demonstrated by at least ONE of the following exams:

**1.1** Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND) with ONE of the following:

- Improvement or maintenance of previous improvement of at least a 4-point increase in score from pretreatment baseline
- Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so

**OR**

**1.2** Hammersmith Infant Neurological Exam Part 2 (HINE-2) with ONE of the following:

- Improvement or maintenance of previous improvement of at least a 2-point (or maximal score) increase in ability to kick
- Improvement or maintenance of previous improvement of at least a 1-point increase in any other HINE-2 milestone (e.g., head control, rolling, sitting, crawling, etc.), excluding voluntary grasp
- The patient exhibited improvement, or maintenance of previous improvement, in more HINE motor milestones than worsening, from pretreatment baseline (net positive improvement)
- Patient has achieved and maintained any new motor milestones when they would otherwise be unexpected to do so

**OR**

**1.3** Hammersmith Functional Motor Scale Expanded (HFMSE) with ONE of the following:

- Improvement or maintenance of previous improvement of at least a 3-point increase in score from pretreatment baseline
- Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so

**OR**

**1.4 Revised Upper Limb Module (RULM) with ONE of the following:**

- Improvement or maintenance of previous improvement of at least a 2-point increase in score from pretreatment baseline
- Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so

**OR**

**1.5 Motor Function Measure 32 (MFM-32) with ONE of the following:**

- Improvement or maintenance of previous improvement of at least a 3-point increase in score from pretreatment baseline
- Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so

**AND**

**2 - Patient is not dependent on invasive ventilation**

**AND**

**3 - Patient is not dependent on the use of non-invasive ventilation beyond use for naps and nighttime sleep**

**AND**

**4 - Patient is not receiving concomitant chronic SMN-modifying therapy [e.g., Spinraza (nusinersen)]**

**AND**

**5 - Prescribed by or in consultation with a neurologist with expertise in the treatment of spinal muscular atrophy (SMA)**

## **2 . Revision History**

| Date      | Notes                                                                                                                                                                                                     |
|-----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 4/28/2025 | Updated GPIs and formularies. Revised criteria for patients that have documented decline from pretreatment baseline status following administration of gene replacement therapy. Removed trach dependence |

Exkivity



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-118602                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Guideline Name</b> | Exkivity                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 2/1/2023 |
|-----------------|----------|

## 1 . Criteria

|                       |                                    |
|-----------------------|------------------------------------|
| Product Name:Exkivity |                                    |
| Diagnosis             | Non-Small Cell Lung Cancer (NSCLC) |
| Approval Length       | 12 month(s)                        |
| Therapy Stage         | Initial Authorization              |
| Guideline Type        | Prior Authorization                |

**Approval Criteria**

**1** - Diagnosis of non-small cell lung cancer (NSCLC)

**AND**

**2** - Disease is locally advanced or metastatic

**AND**

**3** - Disease is epidermal growth factor receptor (EGFR) exon 20 insertion mutation positive

**AND**

**4** - Subsequent therapy for disease that has progressed on or after platinum-based chemotherapy

|                                                                                                                                   |                                    |
|-----------------------------------------------------------------------------------------------------------------------------------|------------------------------------|
| Product Name:Exkivity                                                                                                             |                                    |
| Diagnosis                                                                                                                         | Non-Small Cell Lung Cancer (NSCLC) |
| Approval Length                                                                                                                   | 12 month(s)                        |
| Therapy Stage                                                                                                                     | Reauthorization                    |
| Guideline Type                                                                                                                    | Prior Authorization                |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Patient does not show evidence of progressive disease while on Exkivity therapy</p> |                                    |

|                       |                          |
|-----------------------|--------------------------|
| Product Name:Exkivity |                          |
| Diagnosis             | NCCN Recommended Regimen |
| Approval Length       | 12 month(s)              |

|                                                                                                                                                |                       |
|------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                                                                                  | Initial Authorization |
| Guideline Type                                                                                                                                 | Prior Authorization   |
| <b>Approval Criteria</b><br><br><b>1</b> - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium |                       |

|                                                                                                            |                          |
|------------------------------------------------------------------------------------------------------------|--------------------------|
| Product Name:Exkivity                                                                                      |                          |
| Diagnosis                                                                                                  | NCCN Recommended Regimen |
| Approval Length                                                                                            | 12 month(s)              |
| Therapy Stage                                                                                              | Reauthorization          |
| Guideline Type                                                                                             | Prior Authorization      |
| <b>Approval Criteria</b><br><br><b>1</b> - Documentation of positive clinical response to Exkivity therapy |                          |

## 2 . Revision History

| Date       | Notes                                     |
|------------|-------------------------------------------|
| 12/20/2022 | Updated formularies, cleaned up criteria. |

Fabhalta



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-322189                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Guideline Name</b> | Fabhalta                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 8/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                       |                                           |
|-----------------------|-------------------------------------------|
| Product Name:Fabhalta |                                           |
| Diagnosis             | Paroxysmal nocturnal hemoglobinuria (PNH) |
| Approval Length       | 12 month(s)                               |



|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                       |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Submission of medical records (e.g., chart notes, laboratory values, etc.) documenting the diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) as confirmed by BOTH of the following:</p> <p><b>1.1</b> Flow cytometry analysis confirming presence of PNH clones</p> <p style="text-align: center;"><b>AND</b></p> <p><b>1.2</b> Laboratory results, signs, and/or symptoms attributed to PNH (e.g., abdominal pain, anemia, dyspnea, extreme fatigue, smooth muscle dystonia, unexplained/unusual thrombosis, hemolysis/hemoglobinuria, kidney disease, pulmonary hypertension, etc.)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - ONE of the following:</p> <p><b>2.1</b> Patient will not be prescribed Fabhalta in combination with another complement inhibitor used for the treatment of PNH (e.g., Empaveli, PiaSky, eculizumab, Ultomiris)</p> <p style="text-align: center;"><b>OR</b></p> <p><b>2.2</b> Patient is currently receiving another complement inhibitor (e.g., Empaveli, PiaSky, eculizumab, Ultomiris) which will be discontinued and Fabhalta will be initiated in accordance with the United States Food and Drug Administration approved labeling</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Prescribed by, or in consultation with, ONE of the following:</p> <ul style="list-style-type: none"> <li>• Hematologist</li> <li>• Oncologist</li> </ul> |                       |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|
| Product Name:Fabhalta                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                           |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Paroxysmal nocturnal hemoglobinuria (PNH) |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 12 month(s)                               |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Reauthorization                           |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Prior Authorization                       |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of positive clinical response to Fabhalta therapy (e.g., increased or stabilization of hemoglobin levels, reduction in transfusions, improvement in hemolysis, decrease in LDH, increased reticulocyte count, etc.)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Patient is not receiving Fabhalta in combination with another complement inhibitor used for the treatment of PNH (e.g., Empaveli, PiaSky, eculizumab, Ultomiris)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Prescribed by, or in consultation with, ONE of the following:</p> <ul style="list-style-type: none"> <li>• Hematologist</li> <li>• Oncologist</li> </ul> |                                           |

|                                                                                                                                      |                                             |
|--------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|
| Product Name:Fabhalta                                                                                                                |                                             |
| Diagnosis                                                                                                                            | Primary immunoglobulin A nephropathy (IgAN) |
| Approval Length                                                                                                                      | 12 month(s)                                 |
| Therapy Stage                                                                                                                        | Initial Authorization                       |
| Guideline Type                                                                                                                       | Prior Authorization                         |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of primary immunoglobulin A nephropathy (IgAN) confirmed by renal biopsy</p> |                                             |

**AND**

**2** - Patient is at risk of rapid disease progression [e.g., generally a urine protein-to-creatinine ratio (UPCR) greater than or equal to 1.5 g/g, or by other criteria such as clinical risk scoring using the International IgAN Prediction Tool]

**AND**

**3** - Used to reduce proteinuria

**AND**

**4** - Estimated glomerular filtration rate (eGFR) greater than or equal to 30 mL/min/1.73 m<sup>2</sup>

**AND**

**5** - ONE of the following:

**5.1** Patient is on a stabilized dose and receiving concomitant therapy with ONE of the following as confirmed by claims history or submission of medical records:

- Maximally tolerated angiotensin converting enzyme (ACE) inhibitor (e.g., captopril, enalapril)
- Maximally tolerated angiotensin II receptor blocker (ARB) (e.g., candesartan, valsartan)

**OR**

**5.2** Patient has an allergy, contraindication, or intolerance to ACE inhibitors and ARBs (please specify allergy, contraindication, or intolerance)

**AND**

**6** - ONE of the following:

**6.1** Patient is on a stabilized dose and receiving concomitant therapy with a maximally

tolerated sodium-glucose cotransporter-2 (SGLT2) inhibitor [e.g., Jardiance (empagliflozin)] as confirmed by claims history or submission of medical records

**OR**

**6.2** Patient has an allergy, contraindication, or intolerance to SGLT2 inhibitors (please specify allergy, contraindication, or intolerance)

**AND**

**7** - ONE of the following:

**7.1** Failure to a 30-day trial of a glucocorticoid (e.g., methylprednisolone, prednisone) as confirmed by claims history or submission of medical records

**OR**

**7.2** History of intolerance or contraindication to a glucocorticoid (please specify intolerance or contraindication)

**AND**

**8** - Prescribed by or in consultation with a nephrologist

|                                                                                                                                                                                                                                     |                                   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|
| Product Name: Fabhalta                                                                                                                                                                                                              |                                   |
| Diagnosis                                                                                                                                                                                                                           | Complement 3 glomerulopathy (C3G) |
| Approval Length                                                                                                                                                                                                                     | 12 month(s)                       |
| Therapy Stage                                                                                                                                                                                                                       | Initial Authorization             |
| Guideline Type                                                                                                                                                                                                                      | Prior Authorization               |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of complement 3 glomerulopathy (C3G) confirmed by all of the following:</p> <p><b>1.1</b> Documentation of a kidney biopsy demonstrating characteristic findings of C3G</p> |                                   |

**AND**

**1.2** Glomerulonephritis has persisted at least 3 months in duration

**AND**

**1.3** ONE of the following:

- Serum complement 3 (C3) protein less than 77 mg/dL (alternatively, less than 0.85 x lower limit of the central laboratory normal range)
- Other complement abnormalities are present [e.g., soluble membrane attack complex (sC5b-9), serum factor H, serum factor B, factor I, membrane cofactor protein (MCP, CD46), C3/C4/C5 nephritic factor (NeF)] which are suggestive of a C3 glomerulopathy

**AND**

**1.4** Presence of monoclonal gammopathy of undetermined significance (MGUS) has been excluded by measurement of serum free light chains or other investigative means based on standards of care

**AND**

**2** - Disease is considered to be moderate to severe based on proteinuria greater than or equal to 1.5 g/day and/or abnormal kidney function

**AND**

**3** - Used to reduce proteinuria

**AND**

**4** - ONE of the following:

- Failure to a glucocorticoid (e.g., methylprednisolone, prednisone) as confirmed by claims history or submission of medical records

- History of intolerance or contraindication to a glucocorticoid (please specify intolerance or contraindication)

**AND**

**5 - ONE of the following:**

**5.1** Patient is on a stabilized dose and receiving concomitant therapy with ONE of the following as confirmed by claims history or submission of medical records:

- Maximally tolerated angiotensin converting enzyme (ACE) inhibitor (e.g., captopril, enalapril)
- Maximally tolerated angiotensin II receptor blocker (ARB) (e.g., candesartan, valsartan)

**OR**

**5.2** Patient has an allergy, contraindication, or intolerance to ACE inhibitors and ARBs (please specify allergy, contraindication, or intolerance)

**AND**

**6 - Patient has NOT undergone a solid-organ or cell transplant, including kidney transplant**

**AND**

**7 - Prescribed by or in consultation with a nephrologist**

| Product Name: Fabhalta |                                                                                |
|------------------------|--------------------------------------------------------------------------------|
| Diagnosis              | Primary immunoglobulin A nephropathy (IgAN), Complement 3 glomerulopathy (C3G) |
| Approval Length        | 12 month(s)                                                                    |
| Therapy Stage          | Reauthorization                                                                |
| Guideline Type         | Prior Authorization                                                            |
|                        |                                                                                |

### Approval Criteria

1 - Documentation of positive clinical response to Fabhalta therapy demonstrated by a reduction in proteinuria

## 2 . Revision History

| Date     | Notes                                                                                                                                          |
|----------|------------------------------------------------------------------------------------------------------------------------------------------------|
| 7/7/2025 | Updated formularies. Added criteria for C3 glomerulopathy (C3G). Replaced Soliris with eculizumab in list of examples of complement inhibitors |

Fasenra



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-376242                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Guideline Name</b> | Fasenra                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 10/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                          |                                                                 |
|--------------------------|-----------------------------------------------------------------|
| Product Name:Fasenra Pen |                                                                 |
| Diagnosis                | Severe Asthma                                                   |
| Approval Length          | 12 month(s)                                                     |
| Therapy Stage            | Initial Authorization - Transitioning from UHC medical benefits |
| Guideline Type           | Prior Authorization                                             |



### **Approval Criteria**

**1** - Patient has been established on therapy with Fasenra under an active UnitedHealthcare medical benefit prior authorization for the treatment of severe asthma

**AND**

**2** - Documentation of positive clinical response to Fasenra therapy as demonstrated by ONE of the following:

- Reduction in the frequency of exacerbations
- Decreased utilization of rescue medications
- Increase in percent predicted forced expiratory volume in 1 second (FEV1) from pretreatment baseline
- Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.)
- Reduction in oral corticosteroid requirements

**AND**

**3** - Fasenra is being used in combination with an inhaled corticosteroid (ICS)-containing maintenance medication [e.g., Advair/AirDuo (fluticasone/salmeterol), Breo Ellipta (fluticasone furoate/vilanterol), Symbicort (budesonide/ formoterol), Trelegy Ellipta (fluticasone furoate/umeclidinium/vilanterol)]

**AND**

**4** - Patient is NOT receiving Fasenra in combination with any of the following for treatment of the same indication:

- Anti-interleukin 5 therapy [e.g., Cinqair (reslizumab), Nucala (mepolizumab)]
- Anti-IgE (immunoglobulin E) therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

**AND**

**5** - Prescribed by ONE of the following:

- Allergist
- Immunologist
- Pulmonologist

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                     |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------|
| Product Name:Fasenra Pen                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                     |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Severe Asthma                                                       |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 12 month(s)                                                         |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Initial Authorization – Not transitioning from UHC medical benefits |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Prior Authorization                                                 |
| <p><b>Approval Criteria</b></p> <p><b>1 - Diagnosis of severe asthma</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>2 - Classification of asthma as uncontrolled or inadequately controlled as defined by ONE of the following:</b></p> <ul style="list-style-type: none"> <li>• Poor symptom control [e.g., Asthma Control Questionnaire (ACQ) score consistently greater than 1.5 or Asthma Control Test (ACT) score consistently less than 20]</li> <li>• Two or more bursts of systemic corticosteroids for at least 3 days each in the previous 12 months</li> <li>• Asthma-related emergency treatment (e.g., emergency room visit, hospital admission, or unscheduled physician's office visit for nebulizer or other urgent treatment)</li> <li>• Airflow limitation [e.g., after appropriate bronchodilator withhold forced expiratory volume in 1 second (FEV1) less than 80% predicted (in the face of reduced FEV1/forced vital capacity [FVC] defined as less than the lower limit of normal)]</li> <li>• Patient is currently dependent on oral corticosteroids for the treatment of asthma</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>3 - Submission of medical records (e.g., chart notes, laboratory values, etc.) confirming asthma is an eosinophilic phenotype as defined by a baseline (pre-treatment) peripheral blood eosinophil level greater than or equal to 150 cells per microliter</b></p> |                                                                     |

**AND**

**4** - Fasenra will be used in combination with ONE of the following:

**4.1** ONE maximally-dosed (appropriately adjusted for age) combination inhaled corticosteroid (ICS)/long-acting beta2 agonist (LABA) [e.g., fluticasone/salmeterol (authorized generic of AirDuo), fluticasone propionate/salmeterol diskus (generic for Advair Diskus), Wixela Inhub (generic for Advair Diskus), Advair/AirDuo Respiclick (fluticasone propionate/salmeterol), Symbicort (budesonide/formoterol), Breo Ellipta (fluticasone furoate/vilanterol), Dulera (mometasone/formoterol)]

**OR**

**4.2** Combination therapy including BOTH of the following:

- ONE maximally-dosed (appropriately adjusted for age) ICS product [e.g., ciclesonide (Alvesco), mometasone furoate (Asmanex), beclomethasone dipropionate (QVAR), Arnuity Ellipta (fluticasone furoate)]
- ONE additional asthma controller medication [e.g., LABA - Striverdi (olodaterol) or Arcapta (indacaterol); leukotriene receptor antagonist - montelukast (Singulair); theophylline]

**AND**

**5** - Patient is NOT receiving Fasenra in combination with any of the following for treatment of the same indication:

- Anti-interleukin 5 therapy [e.g., Cinqair (reslizumab), Nucala (mepolizumab)]
- Anti-IgE (immunoglobulin E) therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

**AND**

**6** - Prescribed by ONE of the following:

- Allergist
- Immunologist
- Pulmonologist

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                     |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Fasenra Pen                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                     |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Severe Asthma       |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 12 month(s)         |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of positive clinical response as demonstrated by at least ONE of the following:</p> <ul style="list-style-type: none"> <li>• Reduction in the frequency of exacerbations</li> <li>• Decreased utilization of rescue medications</li> <li>• Increase in percent predicted FEV1 (forced expiratory volume in 1 second) from pretreatment baseline</li> <li>• Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.)</li> <li>• Reduction in oral corticosteroid requirements</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Used in combination with an inhaled corticosteroid (ICS)-containing maintenance medication [e.g., Advair/AirDuo (fluticasone/salmeterol), Breo Ellipta (fluticasone furoate/vilanterol), Symbicort (budesonide/ formoterol), Trelegy Ellipta (fluticasone furoate/umeclidinium/vilanterol)]</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Patient is NOT receiving Fasenra in combination with any of the following for treatment of the same indication:</p> <ul style="list-style-type: none"> <li>• Anti-interleukin 5 therapy [e.g., Cinqair (reslizumab), Nucala (mepolizumab)]</li> <li>• Anti-IgE (immunoglobulin E) therapy [e.g., Xolair (omalizumab)]</li> <li>• Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]</li> <li>• Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]</li> </ul> |                     |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------|
| Product Name:Fasenra Pen                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                 |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Eosinophilic granulomatosis with polyangiitis (EGPA)            |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 12 month(s)                                                     |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Initial Authorization - Transitioning from UHC medical benefits |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Prior Authorization                                             |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Patient has been established on therapy with Fasenra under an active UnitedHealthcare medical benefit prior authorization for the treatment of Eosinophilic granulomatosis with polyangiitis (EGPA)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Documentation of positive clinical response to Fasenra therapy as demonstrated by ONE of the following:</p> <ul style="list-style-type: none"> <li>• Reduction in the frequency and/or severity of relapses</li> <li>• Reduction or discontinuation of doses of corticosteroids and/or immunosuppressant</li> <li>• Disease remission</li> <li>• Reduction in severity or frequency of EGPA-related symptoms</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Patient is NOT receiving Fasenra in combination with any of the following for treatment of the same indication:</p> <ul style="list-style-type: none"> <li>• Anti-interleukin 5 therapy [e.g., Cinqair (reslizumab), Nucala (mepolizumab)]</li> <li>• Anti-IgE (immunoglobulin E) therapy [e.g., Xolair (omalizumab)]</li> <li>• Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]</li> <li>• Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>4</b> - Prescribed by ONE of the following:</p> <ul style="list-style-type: none"> <li>• Pulmonologist</li> <li>• Rheumatologist</li> </ul> |                                                                 |

- Allergist
- Immunologist

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                     |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------|
| Product Name:Fasenra Pen                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                     |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Eosinophilic granulomatosis with polyangiitis (EGPA)                |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 12 month(s)                                                         |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Initial Authorization – Not transitioning from UHC medical benefits |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Prior Authorization                                                 |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of relapsing or refractory Eosinophilic granulomatosis with polyangiitis (EGPA)</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Past medical history or presence of asthma</p> <p style="text-align: center;"><b>AND</b></p> <p>3 - TWO of the following:</p> <ul style="list-style-type: none"> <li>• Histopathological evidence of eosinophilic vasculitis</li> <li>• Histopathological evidence of perivascular eosinophilic infiltration</li> <li>• Histopathological evidence of eosinophil-rich granulomatous inflammation</li> <li>• Neuropathy, mono or poly (motor deficit or nerve conduction abnormality)</li> <li>• Pulmonary infiltrates, non-fixed</li> <li>• Sino-nasal abnormality</li> <li>• Cardiomyopathy (established by echocardiography or MRI)</li> <li>• Glomerulonephritis (hematuria, red cell casts, proteinuria)</li> <li>• Alveolar hemorrhage</li> <li>• Palpable purpura</li> <li>• Anti-neutrophil cytoplasmic antibody (ANCA) positive</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p>4 - History of relapsing or refractory disease defined as one of the following:</p> |                                                                     |

- Relapsing disease as defined as a past history (within the past 2 years) of at least one EGPA relapse (requiring additional or dose escalation of corticosteroids or immunosuppressant, or hospitalization)
- Refractory disease as defined as failure to attain remission within the prior 6 months following induction treatment with standard therapy regimens

**AND**

**5** - Patient is currently taking standard therapy [i.e., systemic glucocorticoids (e.g., prednisone, methylprednisolone) with or without immunosuppressive therapy (e.g., cyclophosphamide, rituximab)]

**AND**

**6** - Patient is NOT receiving Fasenra in combination with any of the following for treatment of the same indication:

- Anti-interleukin 5 therapy [e.g., Cinqair (reslizumab), Nucala (mepolizumab)]
- Anti-IgE (immunoglobulin E) therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

**AND**

**7** - Prescribed by ONE of the following:

- Pulmonologist
- Rheumatologist
- Allergist
- Immunologist

| Product Name:Fasenra Pen |                                                      |
|--------------------------|------------------------------------------------------|
| Diagnosis                | Eosinophilic granulomatosis with polyangiitis (EGPA) |
| Approval Length          | 12 month(s)                                          |
| Therapy Stage            | Reauthorization                                      |
| Guideline Type           | Prior Authorization                                  |

### Approval Criteria

**1** - Documentation of positive clinical response as demonstrated by at least ONE of the following:

- Reduction in the frequency and/or severity of relapses
- Reduction or discontinuation of doses of corticosteroids and/or immunosuppressant
- Disease remission
- Reduction in severity or frequency of EGPA-related symptoms

**AND**

**2** - Patient is NOT receiving Fasenra in combination with any of the following for treatment of the same indication:

- Anti-interleukin 5 therapy [e.g., Cinqair (reslizumab), Nucala (mepolizumab)]
- Anti-IgE (immunoglobulin E) therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

## 2 . Revision History

| Date      | Notes                                                                                                   |
|-----------|---------------------------------------------------------------------------------------------------------|
| 8/28/2025 | Updated formularies. Added new indication and criteria for EGPA. Updated statement for concomitant use. |



Fentanyl IR



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-450262                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Guideline Name</b> | Fentanyl IR                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 12/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                                        |                     |
|----------------------------------------|---------------------|
| Product Name:Fentanyl citrate lozenges |                     |
| Approval Length                        | 12 month(s)         |
| Guideline Type                         | Prior Authorization |
| Approval Criteria                      |                     |

**1** - Submission of medical records demonstrating use is for the management of breakthrough pain associated with a cancer diagnosis (cancer diagnosis must be documented)

**AND**

**2** - Patient must have at least a one week history of ONE of the following medications to demonstrate tolerance to opioids (Document drug and date of trial):

- Oral morphine sulfate at a dose of greater than or equal to 60 mg/day
- Fentanyl transdermal patch at a dose of greater than or equal to 25 mcg/hr
- Oral oxycodone at a dose of greater than or equal to 30 mg/day
- Oral hydromorphone at a dose of greater than or equal to 8 mg/day
- Oral oxymorphone at a dose of greater than or equal to 25 mg/day
- Oral hydrocodone at a dose of greater than or equal to 60 mg/day
- An alternative opioid at an equianalgesic dose (e.g., oral methadone greater than or equal to 20 mg/day)

**AND**

**3** - The patient is currently taking a long-acting opioid around the clock for cancer pain (Document drug)

**AND**

**4** - ONE of the following:

**4.1** The patient is not concurrently receiving an alternative fentanyl transmucosal product

**OR**

**4.2** BOTH of the following:

**4.2.1** The patient is currently receiving an alternative transmucosal fentanyl product

**AND**

**4.2.2** The prescriber is requesting the termination of all current authorizations for alternative transmucosal fentanyl products in order to begin treatment with the requested medication

(Only one transmucosal fentanyl product will be approved at a time. If previous authorizations cannot be terminated, the PA request will be denied)

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                     |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name: Brand Fentora, fentanyl citrate buccal tablet (authorized generic of Fentora)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                     |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 12 month(s)         |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Submission of medical records demonstrating use is for the management of breakthrough pain associated with a cancer diagnosis (cancer diagnosis must be documented)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Patient must have at least a one week history of ONE of the following medications to demonstrate tolerance to opioids (Document drug and date of trial):</p> <ul style="list-style-type: none"> <li>• Oral morphine sulfate at a dose of greater than or equal to 60 mg/day</li> <li>• Fentanyl transdermal patch at a dose of greater than or equal to 25 mcg/hr</li> <li>• Oral oxycodone at a dose of greater than or equal to 30 mg/day</li> <li>• Oral hydromorphone at a dose of greater than or equal to 8 mg/day</li> <li>• Oral oxymorphone at a dose of greater than or equal to 25 mg/day</li> <li>• Oral hydrocodone at a dose of greater than or equal to 60 mg/day</li> <li>• An alternative opioid at an equianalgesic dose (e.g., oral methadone greater than or equal to 20 mg/day)</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - The patient is currently taking a long-acting opioid around the clock for cancer pain (Document drug)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>4</b> - ONE of the following:</p> <p><b>4.1</b> The patient is not concurrently receiving an alternative fentanyl transmucosal product</p> |                     |

**OR**

**4.2** BOTH of the following:

**4.2.1** The patient is currently receiving an alternative fentanyl transmucosal product

**AND**

**4.2.2** The prescriber is requesting the termination of all current authorizations for alternative transmucosal fentanyl products in order to begin treatment with the requested medication (Only one transmucosal fentanyl product will be approved at a time. If previous authorizations cannot be terminated, the PA request will be denied)

**AND**

**5** - One of the following:

- Failure to fentanyl citrate lozenges confirmed by claims history or submission of medical records
- History of intolerance or contraindication to fentanyl citrate lozenges (document intolerance or contraindication)

## 2 . Revision History

| Date       | Notes                |
|------------|----------------------|
| 11/17/2025 | Removed brand Actiq. |

Filspari



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-422552                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Guideline Name</b> | Filspari                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Michigan (ACUMI)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Pennsylvania (ACUPA)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 11/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                       |                       |
|-----------------------|-----------------------|
| Product Name:Filspari |                       |
| Approval Length       | 12 month(s)           |
| Therapy Stage         | Initial Authorization |

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Prior Authorization |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of primary immunoglobulin A nephropathy (IgAN) confirmed by renal biopsy</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Patient is at risk of disease progression</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Used to slow kidney function decline</p> <p style="text-align: center;"><b>AND</b></p> <p><b>4</b> - Used to reduce proteinuria</p> <p style="text-align: center;"><b>AND</b></p> <p><b>5</b> - Estimated glomerular filtration rate (eGFR) greater than or equal to 30 mL/min/1.73 m<sup>2</sup></p> <p style="text-align: center;"><b>AND</b></p> <p><b>6</b> - BOTH of the following:</p> <p><b>6.1</b> Patient is on a maximized stable dose with ONE of the following prior to initiating therapy confirmed by claims history or submitted medical records:</p> <ul style="list-style-type: none"> <li>• Maximally tolerated angiotensin converting enzyme (ACE) inhibitor (e.g., captopril, enalapril)</li> <li>• Maximally tolerated angiotensin II receptor blocker (ARB) (e.g., candesartan, valsartan)</li> </ul> |                     |

**AND**

**6.2** Use of renin-angiotensin-aldosterone system (RAAS) inhibitors (e.g., ACE inhibitors, ARBs), endothelin receptor antagonists [(ERAs) e.g., Letairis, Opsumit, Tracleer)], and Tekturna will be discontinued prior to initiating treatment

**AND**

**7** - ONE of the following:

**7.1** Failure to BOTH of the following confirmed by claims history or submitted medical records

- 30-day trial of a glucocorticoid (e.g., methylprednisolone, prednisone)
- 30-day trial of a SGLT2 inhibitor (e.g., dapagliflozin)

**OR**

**7.2** History of contraindication or intolerance to BOTH of the following (please specify intolerance or contraindication)

- 30-day trial of a glucocorticoid (e.g., methylprednisolone, prednisone)
- 30-day trial of a SGLT2 inhibitor (e.g., dapagliflozin)

**AND**

**8** - Prescribed by or in consultation with a nephrologist

|                                                                                                                                          |                     |
|------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Filspari                                                                                                                    |                     |
| Approval Length                                                                                                                          | 12 month(s)         |
| Therapy Stage                                                                                                                            | Reauthorization     |
| Guideline Type                                                                                                                           | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of positive clinical response demonstrated by a reduction in proteinuria</p> |                     |

## 2 . Revision History

| Date       | Notes                                                   |
|------------|---------------------------------------------------------|
| 10/22/2025 | Updated formularies to include PA-CAID for eff 11/1/25. |



Filsuvez



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-260203                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Guideline Name</b> | Filsuvez                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 7/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                       |                       |
|-----------------------|-----------------------|
| Product Name:Filsuvez |                       |
| Approval Length       | 12 month(s)           |
| Therapy Stage         | Initial Authorization |

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Prior Authorization |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Patient is at least 6 months of age or older</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - One of the following diagnoses:</p> <ul style="list-style-type: none"> <li>• Dystrophic epidermolysis bullosa (DEB)</li> <li>• Junctional epidermolysis bullosa (JEB)</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Submission of medical records (e.g., chart notes, laboratory values) confirming a genetic mutation associated with DEB or JEB (i.e., COL7A1, LAMA3, LAMB3, LAMC2, COL17A1, ITGA6, ITGB4, ITGA3)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>4</b> - Patient has at least one partial thickness wound that meets ALL of the following criteria:</p> <ul style="list-style-type: none"> <li>• 10-50 cm<sup>2</sup> in size</li> <li>• Present for at least 3 weeks</li> <li>• Adequate granulation tissue</li> <li>• Excellent vascularization</li> <li>• No evidence of active wound infection</li> <li>• No evidence or history of basal or squamous cell carcinomas (SCC)</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>5</b> - Prescribed by, or in consultation with, a dermatologist with expertise in the treatment of epidermolysis bullosa (EB)</p> <p style="text-align: center;"><b>AND</b></p> |                     |

**6** - Patient is NOT receiving Filsuvez in combination with Vyjuvek on the same wound(s)

**Product Name:**Filsuvez

**Approval Length** 12 month(s)

**Therapy Stage** Reauthorization

**Guideline Type** Prior Authorization

### Approval Criteria

**1** - Documentation of positive clinical response to Filsuvez therapy (e.g., complete wound closure, reduction in wound size, decrease in procedural pain, less frequent dressing changes, decreased total body wound burden)

**AND**

**2** - Wound(s) being treated meets ALL of the following criteria:

- Adequate granulation tissue
- Excellent vascularization
- No evidence of active wound infection
- No evidence or history of basal or squamous cell carcinomas (SCC)

**AND**

**3** - Filsuvez is prescribed by, or in consultation with, a dermatologist with expertise in the treatment of epidermolysis bullosa (EB)

**AND**

**4** - Patient is not receiving Filsuvez in combination with Vyjuvek on the same wound(s)

## 2 . Revision History

UnitedHealthcare Community Plan of New Jersey – Clinical Pharmacy Guidelines

| Date      | Notes               |
|-----------|---------------------|
| 5/13/2025 | Updated formularies |

Firazyr, Sajazir



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-249242                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Guideline Name</b> | Firazyr, Sajazir                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State Michigan (ACUMI)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 7/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                                                        |                             |
|--------------------------------------------------------|-----------------------------|
| Product Name:Sajazir, Brand Firazyr, generic icatibant |                             |
| Diagnosis                                              | Hereditary angioedema (HAE) |
| Approval Length                                        | 12 month(s)                 |
| Therapy Stage                                          | Initial Authorization       |
| Guideline Type                                         | Prior Authorization         |

## **Approval Criteria**

**1** - Diagnosis of hereditary angioedema (HAE) as confirmed by ONE of the following:

**1.1** C1 inhibitor (C1-INH) deficiency or dysfunction (Type I or II HAE) as documented by ONE of the following (per laboratory standard):

- C1-INH antigenic level below the lower limit of normal
- C1-INH functional level below the lower limit of normal

**OR**

**1.2** HAE with normal C1 inhibitor levels and ONE of the following:

- Confirmed presence of variant(s) in the gene(s) for factor XII, angiotensin-converting enzyme 1, plasminogen-1, kininogen-1, myoferlin, or heparan sulfate-glucosaminase 3-O-sulfotransferase 6
- Recurring angioedema attacks that are refractory to high-dose antihistamines with confirmed family history of angioedema
- Recurring angioedema attacks that are refractory to high-dose antihistamines with unknown background de-novo mutation(s) (i.e., no family history) (HAE-unknown)

**AND**

**2** - Prescribed for the acute treatment of HAE attacks

**AND**

**3** - Not used in combination with other products indicated for the acute treatment of HAE attacks (e.g., Berinert, Kalbitor, or Ruconest)

**AND**

**4** - Prescribed by ONE of the following:

- Immunologist
- Allergist

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                             |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|
| Product Name:Sajazir, Brand Firazyr, generic icatibant                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                             |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Hereditary angioedema (HAE) |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | 12 month(s)                 |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Reauthorization             |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Prior Authorization         |
| <p><b>Approval Criteria</b></p> <p>1 - Documentation of positive clinical response to therapy</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Prescribed for the acute treatment of hereditary angioedema (HAE) attacks</p> <p style="text-align: center;"><b>AND</b></p> <p>3 - Not used in combination with other products indicated for the acute treatment of HAE attacks (e.g., Berinert, Kalbitor, or Ruconest)</p> <p style="text-align: center;"><b>AND</b></p> <p>4 - Prescribed by ONE of the following:</p> <ul style="list-style-type: none"> <li>• Immunologist</li> <li>• Allergist</li> </ul> |                             |

## 2 . Revision History

| Date      | Notes                                                                                                               |
|-----------|---------------------------------------------------------------------------------------------------------------------|
| 4/30/2025 | Combined formularies. Updated GPI entry for Sajazir due to change to brand status. No changes to clinical criteria. |





Firdapse



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-164742                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Guideline Name</b> | Firdapse                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State Pennsylvania (ACUPA)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 2/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                 |             |
|-----------------|-------------|
| Product Name:   | Firdapse    |
| Approval Length | 12 month(s) |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                       |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Patient has a diagnosis of Lambert-Eaton myasthenic syndrome (LEMS)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Prescribed by or in consultation with a specialist in the treatment of LEMS (e.g., neurologist or oncologist)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Patient is not receiving Firdapse in combination with similar potassium channel blockers [e.g., Ampyra (dalfampridine)]</p> |                       |

|                                                                                                                                                                                                                                                                                                           |                     |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Firdapse                                                                                                                                                                                                                                                                                     |                     |
| Approval Length                                                                                                                                                                                                                                                                                           | 12 month(s)         |
| Therapy Stage                                                                                                                                                                                                                                                                                             | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                                                                            | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of positive clinical response to Firdapse therapy</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Patient is not receiving Firdapse in combination with similar potassium channel blockers [e.g., Ampyra (dalfampridine)]</p> |                     |

## 2 . Revision History

| Date     | Notes                                                                           |
|----------|---------------------------------------------------------------------------------|
| 2/5/2025 | Added Indiana and PA Medicaid formularies. No changes to clinical c<br>riteria. |

Fortamet, Glumetza



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-267202                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Guideline Name</b> | Fortamet, Glumetza                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 7/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                                                                    |                     |
|--------------------------------------------------------------------|---------------------|
| Product Name:generic metformin extended-release (generic Fortamet) |                     |
| Approval Length                                                    | 12 month(s)         |
| Guideline Type                                                     | Prior Authorization |
| Approval Criteria                                                  |                     |

**1** - History of greater than or equal to 12-week trial of metformin extended-release (generic Glucophage XR) as confirmed by claims history or submission of medical records

**AND**

**2** - One of the following:

**2.1** Submission of medical records (e.g. chart notes, laboratory values) documenting an inadequate response to metformin extended-release (generic Glucophage XR) as evidenced by the hemoglobin A1c level being above the patient's goal

**OR**

**2.2** Submission of medical records (e.g. chart notes, laboratory values) documenting an intolerance to metformin extended-release (generic Glucophage XR) which is unable to be resolved with attempts to minimize the adverse effects where appropriate (e.g. dose reduction)

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                     |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Brand Glumetza, generic metformin extended-release (generic Glumetza)                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                     |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 12 month(s)         |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - History of greater than or equal to 12 week trial of metformin extended-release (generic Glucophage XR) as confirmed by claims history or submission of medical records</p> <p><b>AND</b></p> <p><b>2</b> - One of the following:</p> <p><b>2.1</b> Submission of medical records (e.g. chart notes, laboratory values) documenting an inadequate response to metformin extended-release (generic Glucophage XR) as evidenced by the hemoglobin A1c level being above the patient's goal</p> |                     |

**OR**

**2.2** Submission of medical records (e.g. chart notes, laboratory values) documenting an intolerance to metformin extended-release (generic Glucophage XR) which is unable to be resolved with attempts to minimize the adverse effects where appropriate (e.g. dose reduction)

**AND**

**3** - History of greater than or equal to 12 week trial of metformin extended-release (generic Fortamet) as confirmed by claims history or submission of medical records

**AND**

**4** - One of the following:

**4.1** Submission of medical records (e.g. chart notes, laboratory values) documenting an inadequate response to metformin extended-release (generic Fortamet) as evidenced by the hemoglobin A1c level being above the patient's goal

**OR**

**4.2** Submission of medical records (e.g. chart notes, laboratory values) documenting an intolerance to metformin extended-release (generic Fortamet) which is unable to be resolved with attempts to minimize the adverse effects where appropriate (e.g. dose reduction)

**AND**

**5** - Submission of article(s) published in the peer-reviewed medical literature showing that the requested drug is likely to be more efficacious to this patient than metformin extended-release (generic Glucophage XR AND generic Fortamet)

## 2 . Revision History

| Date | Notes |
|------|-------|
|------|-------|

|           |                     |
|-----------|---------------------|
| 5/15/2025 | Updated formularies |
|-----------|---------------------|

Fotivda



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-317191                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Guideline Name</b> | Fotivda                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Arizona (ACUAZ, ACUAZEC)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Washington (ACUWA, ACUWAAHE, ACUWAC)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 8/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                      |                            |
|----------------------|----------------------------|
| Product Name:Fotivda |                            |
| Diagnosis            | Renal Cell Carcinoma (RCC) |
| Approval Length      | 12 month(s)                |



|                                                                                                                                                                                                                                                                                                                                                                                                         |                       |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                           | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                          | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of advanced renal cell carcinoma (RCC)</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - ONE of the following:</p> <ul style="list-style-type: none"> <li>• Disease has relapsed</li> <li>• Disease is refractory</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p>3 - Patient has received two or more prior systemic therapies</p> |                       |

|                                                                                                                           |                            |
|---------------------------------------------------------------------------------------------------------------------------|----------------------------|
| Product Name:Fotivda                                                                                                      |                            |
| Diagnosis                                                                                                                 | Renal Cell Carcinoma (RCC) |
| Approval Length                                                                                                           | 12 month(s)                |
| Therapy Stage                                                                                                             | Reauthorization            |
| Guideline Type                                                                                                            | Prior Authorization        |
| <p><b>Approval Criteria</b></p> <p>1 - Patient does not show evidence of progressive disease while on Fotivda therapy</p> |                            |

|                      |                           |
|----------------------|---------------------------|
| Product Name:Fotivda |                           |
| Diagnosis            | NCCN Recommended Regimens |
| Approval Length      | 12 month(s)               |
| Therapy Stage        | Initial Authorization     |

|                                                                                                                                                |                     |
|------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Guideline Type                                                                                                                                 | Prior Authorization |
| <b>Approval Criteria</b><br><br><b>1</b> - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium |                     |

|                                                                                                           |                           |
|-----------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Fotivda                                                                                      |                           |
| Diagnosis                                                                                                 | NCCN Recommended Regimens |
| Approval Length                                                                                           | 12 month(s)               |
| Therapy Stage                                                                                             | Reauthorization           |
| Guideline Type                                                                                            | Prior Authorization       |
| <b>Approval Criteria</b><br><br><b>1</b> - Documentation of positive clinical response to Fotivda therapy |                           |

## 2 . Revision History

| Date     | Notes                                                                                                 |
|----------|-------------------------------------------------------------------------------------------------------|
| 7/2/2025 | Combined formularies. Added RCC abbreviation in dx header section s. No changes to clinical criteria. |

Fruzaqla



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-217210                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Guideline Name</b> | Fruzaqla                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 5/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                       |                       |
|-----------------------|-----------------------|
| Product Name:Fruzaqla |                       |
| Diagnosis             | Colorectal Cancer     |
| Approval Length       | 12 month(s)           |
| Therapy Stage         | Initial Authorization |

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Prior Authorization |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1 - Diagnosis of colorectal cancer</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>2 - Disease is ONE of the following:</b></p> <ul style="list-style-type: none"> <li>• Advanced</li> <li>• Metastatic</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>3 - Patient has been previously treated with ALL of the following:</b></p> <ul style="list-style-type: none"> <li>• Fluoropyrimidine-based chemotherapy (e.g., capecitabine, 5-FU)</li> <li>• Oxaliplatin-based chemotherapy (e.g., CAPEOX, FOLFOX)</li> <li>• Irinotecan-based chemotherapy (e.g., FOLFIRI, FOLFIRINOX)</li> <li>• Anti-VEGF therapy (e.g., aflibercept, bevacizumab, ramucirumab)</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>4 - ONE of the following:</b></p> <p><b>4.1 BOTH of the following:</b></p> <p><b>4.1.1 Disease is RAS wild-type</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>4.1.2 Patient has been previously treated with an anti-EGFR therapy (e.g., cetuximab, panitumumab)</b></p> <p style="text-align: center;"><b>OR</b></p> |                     |

## 4.2 Disease is not RAS wild-type

|                                                                                                                        |                     |
|------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Fruzaqla                                                                                                  |                     |
| Diagnosis                                                                                                              | Colorectal Cancer   |
| Approval Length                                                                                                        | 12 month(s)         |
| Therapy Stage                                                                                                          | Reauthorization     |
| Guideline Type                                                                                                         | Prior Authorization |
| <b>Approval Criteria</b><br><b>1</b> - Patient does not show evidence of progressive disease while on Fruzaqla therapy |                     |

|                                                                                                                                            |                           |
|--------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Fruzaqla                                                                                                                      |                           |
| Diagnosis                                                                                                                                  | NCCN Recommended Regimens |
| Approval Length                                                                                                                            | 12 month(s)               |
| Therapy Stage                                                                                                                              | Initial Authorization     |
| Guideline Type                                                                                                                             | Prior Authorization       |
| <b>Approval Criteria</b><br><b>1</b> - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium |                           |

|                       |                           |
|-----------------------|---------------------------|
| Product Name:Fruzaqla |                           |
| Diagnosis             | NCCN Recommended Regimens |
| Approval Length       | 12 month(s)               |
| Therapy Stage         | Reauthorization           |
| Guideline Type        | Prior Authorization       |
|                       |                           |

**Approval Criteria**

1 - Documentation of positive clinical response to Fruzaqla therapy

**2 . Revision History**

| Date      | Notes                                                                                                                                            |
|-----------|--------------------------------------------------------------------------------------------------------------------------------------------------|
| 3/17/2025 | Combined formularies. For CRC (initial auth section), minor verbiage update in criterion 2 from “of” to “is” with no changes to clinical intent. |

Furoscix



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-322192                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Guideline Name</b> | Furoscix                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Washington (ACUWA, ACUWAAHE, ACUWAC)</li> <li>• Medicaid - Community &amp; State Pennsylvania (ACUPA)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 8/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                       |            |
|-----------------------|------------|
| Product Name:Furoscix |            |
| Approval Length       | 1 month(s) |

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Prior Authorization |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of ONE of the following:</p> <ul style="list-style-type: none"> <li>Chronic heart failure</li> <li>Chronic kidney disease (CKD)</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Submission of medical records confirming that the patient is established on background loop diuretic therapy (e.g., bumetanide, furosemide, torsemide) for the treatment of edema</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - BOTH of the following:</p> <ul style="list-style-type: none"> <li>Patient does NOT require ongoing emergency care or hospitalization</li> <li>Patient is currently a candidate for parenteral diuresis outside of the hospital</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>4</b> - Furoscix is prescribed by or in consultation with ONE of the following:</p> <ul style="list-style-type: none"> <li>Cardiologist</li> <li>Nephrologist</li> </ul> |                     |

## 2 . Revision History

| Date     | Notes                                                                                              |
|----------|----------------------------------------------------------------------------------------------------|
| 7/8/2025 | Updated formularies. Added CKD diagnosis. Updated prescriber requirement. Removed CrCL requirement |



Galafold



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-135467                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Guideline Name</b> | Galafold                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>•</li> <li>•</li> <li>•</li> <li>•</li> <li>•</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 1/1/2024 |
|-----------------|----------|

## 1 . Criteria

|                       |               |
|-----------------------|---------------|
| Product Name:Galafold |               |
| Diagnosis             | Fabry Disease |
| Approval Length       | 12 month(s)   |

|                                                                                                                                                                                                                                                                                                                                                                                                               |                       |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                 | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of Fabry disease</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Patient has an amenable galactosidase alpha gene (GLA) variant based on in vitro assay data</p> <p style="text-align: center;"><b>AND</b></p> <p>3 - Patient is not receiving Galafold in combination with Fabrazyme (agalsidase beta) or Elfabrio (pegunigalsidase alfa-iwxj)</p> |                       |

|                                                                                                                                                                                                                                                                                               |                     |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Galafold                                                                                                                                                                                                                                                                         |                     |
| Diagnosis                                                                                                                                                                                                                                                                                     | Fabry Disease       |
| Approval Length                                                                                                                                                                                                                                                                               | 12 month(s)         |
| Therapy Stage                                                                                                                                                                                                                                                                                 | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                                                                | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p>1 - Documentation of positive clinical response to Galafold therapy</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Patient is not receiving Galafold in combination with Fabrazyme (agalsidase beta) or Elfabrio (pegunigalsidase alfa-iwxj)</p> |                     |

## 2 . Revision History

| Date       | Notes                                                  |
|------------|--------------------------------------------------------|
| 10/26/2023 | Added Elfabrio as a drug to not be used in combination |

Gattex



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-436478                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Guideline Name</b> | Gattex                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Pennsylvania (ACUPA)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 12/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                 |             |
|-----------------|-------------|
| Product Name:   | Gattex      |
| Approval Length | 12 month(s) |

|                                                                                                                                                                                    |                       |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                                                                                                                      | Initial Authorization |
| Guideline Type                                                                                                                                                                     | Prior Authorization   |
| <b>Approval Criteria</b><br><br><b>1</b> - Diagnosis of Short Bowel Syndrome (SBS)<br><br><p style="text-align: center;"><b>AND</b></p> <b>2</b> - Dependent on parenteral support |                       |

|                                                                                                          |                     |
|----------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Gattex                                                                                      |                     |
| Approval Length                                                                                          | 12 month(s)         |
| Therapy Stage                                                                                            | Reauthorization     |
| Guideline Type                                                                                           | Prior Authorization |
| <b>Approval Criteria</b><br><br><b>1</b> - Documentation of positive clinical response to Gattex therapy |                     |

## 2 . Revision History

| Date       | Notes                                         |
|------------|-----------------------------------------------|
| 10/31/2025 | Combined formularies. No changes to criteria. |

Gavreto



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-163845                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Guideline Name</b> | Gavreto                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 2/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                      |                                    |
|----------------------|------------------------------------|
| Product Name:Gavreto |                                    |
| Diagnosis            | Non-Small Cell Lung Cancer (NSCLC) |
| Approval Length      | 12 month(s)                        |
| Therapy Stage        | Initial Authorization              |
| Guideline Type       | Prior Authorization                |

**Approval Criteria**

**1** - Patient has a diagnosis of non-small cell lung cancer (NSCLC)

**AND**

**2** - Disease is ONE of the following:

- Recurrent
- Advanced
- Metastatic

**AND**

**3** - There is presence of RET rearrangement positive tumors

|                                                                                                                                                                                                                                                                                       |                       |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Gavreto                                                                                                                                                                                                                                                                  |                       |
| Diagnosis                                                                                                                                                                                                                                                                             | Thyroid Carcinoma     |
| Approval Length                                                                                                                                                                                                                                                                       | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                         | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                        | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - ALL of the following:</p> <p><b>1.1</b> Diagnosis of ONE of the following:</p> <ul style="list-style-type: none"> <li>• Follicular carcinoma</li> <li>• Oncocytic carcinoma</li> <li>• Papillary carcinoma</li> </ul> <p><b>AND</b></p> |                       |

**1.2 ONE of the following:**

- Unresectable locoregional recurrent disease
- Persistent disease
- Metastatic disease

**AND**

**1.3 Disease is RET gene fusion positive**

**AND**

**1.4 Disease is not amenable to radioactive iodine therapy**

**OR**

**2 - ALL of the following:**

**2.1 Diagnosis of medullary carcinoma**

**AND**

**2.2 ONE of the following:**

- Disease is recurrent, persistent, or progressive
- Disease is symptomatic with distant metastases

**AND**

**2.3 Disease is RET-mutation positive**

**OR**

**3 - ALL of the following:**

**3.1 Diagnosis of anaplastic carcinoma**



**AND**

**3.2 ONE of the following:**

- Disease is stage IVA or IVB (locoregional)
- Disease is metastatic

**AND**

**3.3 Disease is RET gene fusion positive**

|                                                                                                                                                                                                                                                                                                                                                                            |                       |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Gavreto                                                                                                                                                                                                                                                                                                                                                       |                       |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                  | Hepatobiliary Cancers |
| Approval Length                                                                                                                                                                                                                                                                                                                                                            | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                              | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                             | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1 - ONE of the following:</b></p> <p><b>1.1 BOTH of the following:</b></p> <p><b>1.1.1</b> Diagnosis of gallbladder cancer</p> <p><b>AND</b></p> <p><b>1.1.2</b> Disease is one of the following:</p> <ul style="list-style-type: none"> <li>• Unresectable</li> <li>• Resected gross residual (R2)</li> <li>• Metastatic</li> </ul> |                       |

**OR**

**1.2 BOTH of the following:**

**1.2.1** Diagnosis of cholangiocarcinoma

**AND**

**1.2.2** Disease is one of the following:

- Unresectable
- Resected gross residual (R2)
- Metastatic
- Resectable locoregionally advanced

**AND**

**2** - Disease is positive for RET gene fusion mutation

| Product Name:Gavreto                                                                                                  |                                                                              |
|-----------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------|
| Diagnosis                                                                                                             | Non-Small Cell Lung Cancer (NSCLC), Thyroid Carcinoma, Hepatobiliary Cancers |
| Approval Length                                                                                                       | 12 month(s)                                                                  |
| Therapy Stage                                                                                                         | Reauthorization                                                              |
| Guideline Type                                                                                                        | Prior Authorization                                                          |
| <b>Approval Criteria</b><br><b>1</b> - Patient does not show evidence of progressive disease while on Gavreto therapy |                                                                              |

| Product Name:Gavreto |                           |
|----------------------|---------------------------|
| Diagnosis            | NCCN Recommended Regimens |
| Approval Length      | 12 month(s)               |
| Therapy Stage        | Initial Authorization     |

|                                                                                                                                                |                     |
|------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Guideline Type                                                                                                                                 | Prior Authorization |
| <b>Approval Criteria</b><br><br><b>1</b> - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium |                     |

|                                                                                                           |                           |
|-----------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Gavreto                                                                                      |                           |
| Diagnosis                                                                                                 | NCCN Recommended Regimens |
| Approval Length                                                                                           | 12 month(s)               |
| Therapy Stage                                                                                             | Reauthorization           |
| Guideline Type                                                                                            | Prior Authorization       |
| <b>Approval Criteria</b><br><br><b>1</b> - Documentation of positive clinical response to Gavreto therapy |                           |

## 2 . Revision History

| Date      | Notes                                      |
|-----------|--------------------------------------------|
| 1/15/2025 | Updated criteria for hepatobiliary cancers |

Gilotrif



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-356190                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Guideline Name</b> | Gilotrif                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 9/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                       |                                    |
|-----------------------|------------------------------------|
| Product Name:Gilotrif |                                    |
| Diagnosis             | Non-Small Cell Lung Cancer (NSCLC) |
| Approval Length       | 12 month(s)                        |
| Therapy Stage         | Initial Authorization              |

|                                                                                                                                                                                                                                                                                                                                                                                                                 |                     |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                  | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of metastatic non-small cell lung cancer (NSCLC)</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - ONE of the following:</p> <ul style="list-style-type: none"> <li>Squamous disease progressing after previous platinum-based chemotherapy</li> <li>Tumors are positive for non-resistant epidermal growth factor receptor (EGFR) mutations</li> </ul> |                     |

|                                                                                                                                                                                                                                        |                                         |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|
| Product Name:Gilotrif                                                                                                                                                                                                                  |                                         |
| Diagnosis                                                                                                                                                                                                                              | Non-Nasopharyngeal Head and Neck Cancer |
| Approval Length                                                                                                                                                                                                                        | 12 month(s)                             |
| Therapy Stage                                                                                                                                                                                                                          | Initial Authorization                   |
| Guideline Type                                                                                                                                                                                                                         | Prior Authorization                     |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of advanced, non-nasopharyngeal head and neck cancer</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Disease has progressed on or after platinum-containing chemotherapy</p> |                                         |

|                       |                       |
|-----------------------|-----------------------|
| Product Name:Gilotrif |                       |
| Diagnosis             | Brain Metastases      |
| Approval Length       | 12 month(s)           |
| Therapy Stage         | Initial Authorization |

|                                                                                                                                                                                  |                     |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Guideline Type                                                                                                                                                                   | Prior Authorization |
| <b>Approval Criteria</b><br><br><b>1</b> - Diagnosis of brain metastasis due to EGFR (epidermal growth factor receptor)-sensitizing mutation positive non-small cell lung cancer |                     |

|                                                                                                                            |                                                                                               |
|----------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------|
| Product Name:Gilotrif                                                                                                      |                                                                                               |
| Diagnosis                                                                                                                  | Non-Small Cell Lung Cancer (NSCLC), Non-Nasopharyngeal Head and Neck Cancer, Brain Metastases |
| Approval Length                                                                                                            | 12 month(s)                                                                                   |
| Therapy Stage                                                                                                              | Reauthorization                                                                               |
| Guideline Type                                                                                                             | Prior Authorization                                                                           |
| <b>Approval Criteria</b><br><br><b>1</b> - Patient does not show evidence of progressive disease while on Gilotrif therapy |                                                                                               |

|                                                                                                                                                |                           |
|------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Gilotrif                                                                                                                          |                           |
| Diagnosis                                                                                                                                      | NCCN Recommended Regimens |
| Approval Length                                                                                                                                | 12 month(s)               |
| Therapy Stage                                                                                                                                  | Initial Authorization     |
| Guideline Type                                                                                                                                 | Prior Authorization       |
| <b>Approval Criteria</b><br><br><b>1</b> - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium |                           |

|                       |                           |
|-----------------------|---------------------------|
| Product Name:Gilotrif |                           |
| Diagnosis             | NCCN Recommended Regimens |

|                                                                                                     |                     |
|-----------------------------------------------------------------------------------------------------|---------------------|
| Approval Length                                                                                     | 12 month(s)         |
| Therapy Stage                                                                                       | Reauthorization     |
| Guideline Type                                                                                      | Prior Authorization |
| <b>Approval Criteria</b><br><br>1 - Documentation of positive clinical response to Gilotrif therapy |                     |

## 2 . Revision History

| Date      | Notes                                                                                                                                    |
|-----------|------------------------------------------------------------------------------------------------------------------------------------------|
| 7/31/2025 | Combined formularies. Minor updates to dx headers and updated verbiage in NCCN initial auth section, with no changes to clinical intent. |

GLP-1 & Dual GIP/GLP-1 Receptor Agonists



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-404238                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Guideline Name</b> | GLP-1 & Dual GIP/GLP-1 Receptor Agonists                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 11/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                                                                                                                                     |                     |
|-------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name: Brand Victoza 1.2mg per day (2 Pen Pack), generic liraglutide 1.2mg per day (2 Pen Pack), Mounjaro, Ozempic, Rybelsus |                     |
| Approval Length                                                                                                                     | 12 month(s)         |
| Guideline Type                                                                                                                      | Prior Authorization |
| Approval Criteria                                                                                                                   |                     |



**1** - Submission of medical records (e.g., chart notes) confirming diagnosis of type 2 diabetes mellitus as evidenced by ONE of the following laboratory values:

- A1C greater than or equal to 6.5%
- Fasting plasma glucose (FPG) greater than or equal to 126 milligrams per deciliter (mg/dL)
- 2-hour plasma glucose (PG) greater than or equal to 200 mg/dL during oral glucose tolerance test
- Random plasma glucose greater than or equal to 200 mg/dL in patient with classic symptoms of hyperglycemia or hyperglycemic crisis

**OR**

**2** - For patients requiring ongoing treatment for type 2 diabetes mellitus (i.e., diagnosed greater than 2 years ago), submission of medical records (e.g., chart notes) confirming diagnosis of type 2 diabetes mellitus

Product Name: Brand Victoza 1.8mg per day (3 Pen Pack), generic liraglutide 1.8mg per day (3 Pen Pack)

|                 |                       |
|-----------------|-----------------------|
| Approval Length | 12 month(s)           |
| Therapy Stage   | Initial Authorization |
| Guideline Type  | Prior Authorization   |

### Approval Criteria

**1** - ONE of the following:

**1.1** Submission of medical records (e.g., chart notes) confirming diagnosis of type 2 diabetes mellitus as evidenced by ONE of the following laboratory values:

- A1C greater than or equal to 6.5%
- Fasting plasma glucose (FPG) greater than or equal to 126 milligrams per deciliter (mg/dL)
- 2-hour plasma glucose (PG) greater than or equal to 200 mg/dL during oral glucose tolerance test
- Random plasma glucose greater than or equal to 200 mg/dL in patient with classic symptoms of hyperglycemia or hyperglycemic crisis

**OR**

**1.2** For patients requiring ongoing treatment for type 2 diabetes mellitus (i.e., diagnosed greater than 2 years ago), submission of medical records (e.g., chart notes) confirming diagnosis of type 2 diabetes mellitus

**AND**

**2** - History of failure to achieve acceptable glycemic control with Victoza (brand or generic) 1.2mg per day for 90 days (2 Pen Pack), as confirmed by claims history or submission of medical records

Product Name: Brand Victoza 1.8mg per day (3 Pen Pack), generic liraglutide 1.8mg per day (3 Pen Pack)

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                 |
|---------------|-----------------|
| Therapy Stage | Reauthorization |
|---------------|-----------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

**1** - Documentation of positive clinical response to therapy (e.g., improved A1C)

Product Name: Bydureon BCise, Byetta, Exenatide, Trulicity

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

**1** - ONE of the following:

**1.1** Submission of medical records (e.g., chart notes) confirming diagnosis of type 2 diabetes mellitus as evidenced by ONE of the following laboratory values:

- A1C greater than or equal to 6.5%
- Fasting plasma glucose (FPG) greater than or equal to 126 milligrams per deciliter (mg/dL)
- 2-hour plasma glucose (PG) greater than or equal to 200 mg/dL during oral glucose tolerance test
- Random plasma glucose greater than or equal to 200 mg/dL in patient with classic symptoms of hyperglycemia or hyperglycemic crisis

**OR**

**1.2** For patients requiring ongoing treatment for type 2 diabetes mellitus (i.e., diagnosed greater than 2 years ago), submission of medical records (e.g., chart notes) confirming diagnosis of type 2 diabetes mellitus

**AND**

**2** - ONE of the following:

**2.1** Suboptimal response (i.e., suboptimal glycemic control) to BOTH of the following, each for a minimum of 90 days, as confirmed by claims history or submission of medical records:

- A commercially available semaglutide product indicated for type 2 diabetes mellitus (e.g., Ozempic, Rybelsus)
- Mounjaro

**OR**

**2.2** History of contraindication or intolerance to BOTH of the following (please specify contraindication or intolerance)

- A commercially available semaglutide product indicated for type 2 diabetes mellitus (e.g., Ozempic, Rybelsus)
- Mounjaro

|                                                           |                     |
|-----------------------------------------------------------|---------------------|
| Product Name:Bydureon BCise, Byetta, Exenatide, Trulicity |                     |
| Approval Length                                           | 12 month(s)         |
| Therapy Stage                                             | Reauthorization     |
| Guideline Type                                            | Prior Authorization |

**Approval Criteria**

1 - Documentation of positive clinical response to therapy (e.g., improved A1C)

**2 . Revision History**

| Date      | Notes                                                 |
|-----------|-------------------------------------------------------|
| 10/1/2025 | Updated criteria to include brand or generic Victoza. |

Gomekli



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-267197                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Guideline Name</b> | Gomekli                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Washington (ACUWA, ACUWAAHE, ACUWAC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 7/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                      |                          |
|----------------------|--------------------------|
| Product Name:Gomekli |                          |
| Diagnosis            | Neurofibromatosis Type 1 |
| Approval Length      | 12 month(s)              |

|                                                                                                                                                                                                                                                                                                                                  |                       |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                                                                                                                                                                                                                                                                    | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                   | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of neurofibromatosis type 1</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Patient has plexiform neurofibromas (PN) that are both of the following:</p> <ul style="list-style-type: none"> <li>• Symptomatic</li> <li>• Not amenable to complete resection</li> </ul> |                       |

|                                                                                                                           |                          |
|---------------------------------------------------------------------------------------------------------------------------|--------------------------|
| Product Name:Gomekli                                                                                                      |                          |
| Diagnosis                                                                                                                 | Neurofibromatosis Type 1 |
| Approval Length                                                                                                           | 12 month(s)              |
| Therapy Stage                                                                                                             | Reauthorization          |
| Guideline Type                                                                                                            | Prior Authorization      |
| <p><b>Approval Criteria</b></p> <p>1 - Patient does not show evidence of progressive disease while on Gomekli therapy</p> |                          |

|                      |                           |
|----------------------|---------------------------|
| Product Name:Gomekli |                           |
| Diagnosis            | NCCN Recommended Regimens |
| Approval Length      | 12 month(s)               |
| Therapy Stage        | Initial Authorization     |
| Guideline Type       | Prior Authorization       |
|                      |                           |

**Approval Criteria**

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Gomekli

|                 |                           |
|-----------------|---------------------------|
| Diagnosis       | NCCN Recommended Regimens |
| Approval Length | 12 month(s)               |
| Therapy Stage   | Reauthorization           |
| Guideline Type  | Prior Authorization       |

**Approval Criteria**

1 - Documentation of positive clinical response to Gomekli therapy

## 2 . Revision History

| Date      | Notes                         |
|-----------|-------------------------------|
| 5/14/2025 | Updated formularies to add IN |

Gonadotropin-Releasing Hormone Agonists



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                            |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-161316                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Guideline Name</b> | Gonadotropin-Releasing Hormone Agonists                                                                                                                                                                                                                                                                                                                                                    |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 1/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                                                                                        |                                  |
|----------------------------------------------------------------------------------------|----------------------------------|
| Product Name:leuprolide acetate inj kit 5 mg/mL, Lupron Depot-Ped, Triptodur, Fensolvi |                                  |
| Diagnosis                                                                              | Central Precocious Puberty (CPP) |
| Approval Length                                                                        | 12 month(s)                      |
| Therapy Stage                                                                          | Initial Authorization            |
| Guideline Type                                                                         | Prior Authorization              |
| <b>Approval Criteria</b>                                                               |                                  |



**1** - Diagnosis of central precocious puberty (idiopathic or neurogenic)

**AND**

**2** - Onset of secondary sexual characteristics in **ONE** of the following:

**2.1** Females less than or equal to 8 years of age

**OR**

**2.2** Males less than or equal to 9 years of age

**AND**

**3** - Confirmation of diagnosis as defined by **ONE** of the following:

**3.1** Pubertal basal level of luteinizing hormone (based on laboratory reference ranges)

**OR**

**3.2** A pubertal luteinizing hormone response to a gonadotropin releasing hormone (GnRH) stimulation test

**OR**

**3.3** Bone age advanced one year beyond the chronological age

**AND**

**4** - If the request is for Triptodur or Lupron-Depot Ped (6-month), **ONE** of the following:

**4.1** Failure to Fensolvi as confirmed by claims history or submission of medical records

**OR**

**4.2** History of intolerance or contraindication to Fensolvi (please specify intolerance or contraindication)

|                                                                                        |                                  |
|----------------------------------------------------------------------------------------|----------------------------------|
| Product Name:leuprolide acetate inj kit 5 mg/mL, Lupron Depot-Ped, Triptodur, Fensolvi |                                  |
| Diagnosis                                                                              | Central Precocious Puberty (CPP) |
| Approval Length                                                                        | 12 month(s)                      |
| Therapy Stage                                                                          | Reauthorization                  |
| Guideline Type                                                                         | Prior Authorization              |

**Approval Criteria**

1 - Patient is currently receiving therapy for central precocious puberty

**AND**

2 - Documentation of positive clinical response to therapy (e.g., decrease in height velocity, cessation of menses, arrest pubertal progression, reduction in bone age advancement)

**AND**

3 - Patient is currently younger than the appropriate time point for the onset of puberty, as ONE of the following:

3.1 Female younger than 11 years of age

**OR**

3.2 Male younger than 12 years of age

|                                                        |                       |
|--------------------------------------------------------|-----------------------|
| Product Name:Lupron Depot 3.75 mg and 3-month 11.25 mg |                       |
| Diagnosis                                              | Endometriosis         |
| Approval Length                                        | 6 month(s)            |
| Therapy Stage                                          | Initial Authorization |

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Prior Authorization |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of endometriosis or endometriosis is suspected</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - ONE of the following:</p> <p><b>2.1</b> Failure to BOTH of the following classes as confirmed by claims history or submission of medical records:</p> <ul style="list-style-type: none"> <li>• Oral contraceptives or depot medroxyprogesterone (e.g., Depo-Provera)</li> <li>• Non-steroidal anti-inflammatory drugs (NSAIDs)</li> </ul> <p style="text-align: center;"><b>OR</b></p> <p><b>2.2</b> History of intolerance or contraindication to BOTH of the following classes (please specify intolerance or contraindication):</p> <ul style="list-style-type: none"> <li>• Oral contraceptives or depot medroxyprogesterone (e.g., Depo-Provera)</li> <li>• Non-steroidal anti-inflammatory drugs (NSAIDs)</li> </ul> <p style="text-align: center;"><b>OR</b></p> <p><b>2.3</b> Patient has had surgical ablation to prevent recurrence</p> |                     |

|                                                        |                     |
|--------------------------------------------------------|---------------------|
| Product Name:Lupron Depot 3.75 mg and 3-month 11.25 mg |                     |
| Diagnosis                                              | Endometriosis       |
| Therapy Stage                                          | Reauthorization     |
| Guideline Type                                         | Prior Authorization |
| <p><b>Approval Criteria</b></p>                        |                     |

**1 - Diagnosis of endometriosis or endometriosis is suspected**

**AND**

**2 - Recurrence of symptoms following an initial course of therapy**

**AND**

**3 - Concurrently to be used with add-back therapy (e.g., progestin, estrogen, or bone sparing agents)**

**AND**

**4 - Treatment duration has not exceeded a total of 12 months, as confirmed by claims history or submission of medical records**

|       |                                                                                                                                                                |
|-------|----------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Notes | Approval Length - Authorization will be issued for 6 months. Duration of both the initial and recurrent course of therapies is no longer than 12 months total. |
|-------|----------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                                                                                                                                                                                                                                                   |                                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|
| Product Name:Lupron Depot 3.75 mg and 3-month 11.25 mg                                                                                                                                                                                            |                                |
| Diagnosis                                                                                                                                                                                                                                         | Uterine Leiomyomata (Fibroids) |
| Approval Length                                                                                                                                                                                                                                   | 3 month(s)                     |
| Guideline Type                                                                                                                                                                                                                                    | Prior Authorization            |
| <p><b>Approval Criteria</b></p> <p><b>1 - ALL of the following:</b></p> <p><b>1.1 For the treatment of uterine leiomyomata-related anemia</b></p> <p><b>AND</b></p> <p><b>1.2 Patient did not respond to iron therapy of 1 month duration</b></p> |                                |

**AND**

**1.3** For use prior to surgery

**OR**

**2** - For use prior to surgery to reduce the size of fibroids to facilitate a surgical procedure (e.g., myomectomy, hysterectomy)

Product Name:Lupron Depot 7.5 mg, 22.5 mg, 30 mg, and 45 mg, leuprolide acetate inj kit 5 mg/mL, leuprolide acetate (3 month) 22.5 mg inj

|                |                     |
|----------------|---------------------|
| Diagnosis      | Prostate Cancer     |
| Guideline Type | Prior Authorization |

### Approval Criteria

**1** - For a diagnosis of advanced or metastatic prostate cancer, the requested medication is not delegated to OptumRx for review and should be processed as a medical benefit

Product Name:Lupron Depot, Lupron Depot-Ped, Fensolvi, Triptodur, leuprolide acetate inj kit 5 mg/mL, leuprolide acetate (3 month) 22.5 mg inj

|                 |                                  |
|-----------------|----------------------------------|
| Diagnosis       | Gender Dysphoria in Adolescents* |
| Approval Length | 12 month(s)                      |
| Therapy Stage   | Initial Authorization            |
| Guideline Type  | Prior Authorization              |

### Approval Criteria

**1** - Submission of medical records (e.g., chart notes, laboratory values) documenting a diagnosis of gender dysphoria, according to the current Diagnostic and Statistical Manual of Mental Disorders (i.e., DSM-5) criteria, by a mental health professional with expertise in child and adolescent psychiatry

**AND**

**2** - Submission of medical records (e.g., chart notes, laboratory values) documenting the medication is prescribed by or in consultation with an endocrinologist or a medical provider experienced in gender dysphoria hormone therapy

**AND**

**3** - Submission of medical records (e.g., chart notes, laboratory values) documenting the patient has experienced puberty development to at least Tanner stage 2

**AND**

**4** - Submission of medical records (e.g., chart notes, laboratory values) documenting ONE of the following laboratory tests, based upon the laboratory reference range, confirming:

- Pubertal levels of estradiol in a female
- Pubertal levels of testosterone in a male
- Pubertal basal level of luteinizing hormone (based on laboratory reference ranges)
- A pubertal luteinizing hormone response to a gonadotropin-releasing hormone (GnRH) stimulation test

**AND**

**5** - Submission of medical records (e.g., chart notes, laboratory values) documenting a letter from the prescriber and/or formal documentation stating ALL of the following:

**5.1** Patient has experienced pubertal changes that have resulted in an increase of their gender dysphoria that has significantly impaired psychological or social functioning

**AND**

**5.2** Coexisting psychiatric and medical comorbidities or social problems that may interfere with the diagnostic procedures or treatment have been addressed or removed

**AND**

**5.3 BOTH of the following:**

**5.3.1** Current enrollment, attendance, and active participation in psychological and social support treatment program

**AND**

**5.3.2** Patient will continue enrollment, attendance, and active participation in psychological and social support throughout the course of treatment

**AND**

**5.4** Patient demonstrates knowledge and understanding of the expected outcomes of treatment and related transgender therapies

|       |                                                                         |
|-------|-------------------------------------------------------------------------|
| Notes | *Please verify gender dysphoria is a coverable benefit for the patient. |
|-------|-------------------------------------------------------------------------|

Product Name:Lupron Depot, Lupron Depot-Ped, Fensolvi, Triptodur, leuprolide acetate inj kit 5 mg/mL, leuprolide acetate (3 month) 22.5 mg inj

|           |                                  |
|-----------|----------------------------------|
| Diagnosis | Gender Dysphoria in Adolescents* |
|-----------|----------------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                 |
|---------------|-----------------|
| Therapy Stage | Reauthorization |
|---------------|-----------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

**1** - Submission of medical records (e.g., chart notes, laboratory values) documenting ONE of the following within the last 6 months:

- LH (luteinizing hormone) suppression assessing for appropriate suppression
- Change in dosing

**AND**

**2** - Submission of medical records (e.g., chart notes, laboratory values) documenting diagnosis of gender dysphoria, according to the current Diagnostic and Statistical Manual of

Mental Disorders (i.e., DSM-5) criteria, by a mental health professional with expertise in child and adolescent psychiatry

**AND**

**3** - Submission of medical records (e.g., chart notes, laboratory values) documenting the medication is prescribed by or in consultation with an endocrinologist or a medical provider experienced in gender dysphoria hormone therapy

**AND**

**4** - Submission of medical records (e.g., chart notes, laboratory values) documenting a letter from the prescriber and/or formal documentation stating ALL of the following:

**4.1** Patient continues to meet their individual goals of therapy for gender dysphoria

**AND**

**4.2** Patient continues to have a strong affinity for the desired (opposite of natal) gender

**AND**

**4.3** Discontinuation of treatment and subsequent pubertal development would interfere with or impair psychological functioning and well-being

**AND**

**4.4** Coexisting psychiatric and medical comorbidities or social problems that may interfere with treatment continue to be addressed or removed

**AND**

**4.5** BOTH of the following:

**4.5.1** Current enrollment, attendance, and active participation in psychological and social support treatment program



**AND**

**4.5.2** Patient will continue enrollment, attendance, and active participation in psychological and social support throughout the course of treatment

**AND**

**4.6** Patient demonstrates knowledge and understanding of the expected outcomes of treatment and related transgender therapies

|       |                                                                         |
|-------|-------------------------------------------------------------------------|
| Notes | *Please verify gender dysphoria is a coverable benefit for the patient. |
|-------|-------------------------------------------------------------------------|

Product Name:Lupron Depot, Lupron Depot-Ped, Fensolvi, Triptodur, leuprolide acetate inj kit 5 mg/mL, leuprolide acetate (3 month) 22.5 mg inj

|           |                                                                       |
|-----------|-----------------------------------------------------------------------|
| Diagnosis | Adjunct for Gender-Affirming Hormonal Therapy for Transgender Adults* |
|-----------|-----------------------------------------------------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

### Approval Criteria

**1** - Submission of medical records (e.g., chart notes, laboratory values) documenting a diagnosis of gender dysphoria, according to the current Diagnostic and Statistical Manual of Mental Disorders (i.e., DSM-5) criteria, by a mental health professional

**AND**

**2** - Submission of medical records (e.g., chart notes, laboratory values) documenting the medication is prescribed by or in consultation with an endocrinologist or a medical provider experienced in transgender hormone therapy

**AND**

**3** - Submission of medical records (e.g., chart notes, laboratory values) documenting the gonads (i.e., testes, ovaries) have not been removed and are functional (e.g., hormone producing)

**AND**

**4** - Submission of medical records (e.g., chart notes, laboratory values) documenting the patient is currently receiving hormonal therapy (e.g., testosterone, estrogens, progesterones) to achieve the desired (e.g., non-natal) gender

**AND**

**5** - Submission of medical records (e.g., chart notes, laboratory values) documenting inability of cross sex hormone therapy to inhibit natal secondary sex characteristics, luteinizing hormone (LH), or gonadotropins (e.g., menses, testosterone)

**AND**

**6** - Submission of medical records (e.g., chart notes, laboratory values) documenting a letter from the prescriber and/or formal documentation stating ALL of the following:

**6.1** Transgender patient has identified goals of gender-affirming hormone therapy

**AND**

**6.2** Coexisting psychiatric and medical comorbidities or social problems that may interfere with the diagnostic procedures or treatment have been addressed or removed

**AND**

**6.3** BOTH of the following:

**6.3.1** Current enrollment, attendance, and active participation in psychological and social support treatment program

**AND**

**6.3.2** Patient will continue enrollment, attendance, and active participation in psychological and social support throughout the course of treatment

**AND**

**6.4** Patient demonstrates knowledge and understanding of the expected outcomes of treatment and related transgender therapies

|       |                                                                        |
|-------|------------------------------------------------------------------------|
| Notes | *Please verify gender dysphoria is a coverable benefit for the patient |
|-------|------------------------------------------------------------------------|

Product Name:Lupron Depot, Lupron Depot-Ped, Fensolvi, Triptodur, leuprolide acetate inj kit 5 mg/mL, leuprolide acetate (3 month) 22.5 mg inj

|           |                                                                       |
|-----------|-----------------------------------------------------------------------|
| Diagnosis | Adjunct for Gender-Affirming Hormonal Therapy for Transgender Adults* |
|-----------|-----------------------------------------------------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                 |
|---------------|-----------------|
| Therapy Stage | Reauthorization |
|---------------|-----------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

### Approval Criteria

**1** - Submission of medical records (e.g., chart notes, laboratory values) documenting ONE of the following within the last 6 months:

- Luteinizing hormone (LH) suppression assessing for appropriate suppression
- Change in dosing

**AND**

**2** - Submission of medical records (e.g., chart notes, laboratory values) documenting a diagnosis of gender dysphoria, according to the current Diagnostic and Statistical Manual of Mental Disorders (i.e., DSM-5) criteria, by a mental health professional

**AND**

**3** - Submission of medical records (e.g., chart notes, laboratory values) documenting the

medication is prescribed by or in consultation with an endocrinologist or a medical provider experienced in transgender hormone therapy

**AND**

**4** - Submission of medical records (e.g., chart notes, laboratory values) documenting the gonads (i.e., testes, ovaries) are intact

**AND**

**5** - Submission of medical records (e.g., chart notes, laboratory values) documenting the patient is currently receiving hormonal therapy (e.g., testosterone, estrogens, progesterones) to achieve the desired (e.g., non-natal) gender

**AND**

**6** - Submission of medical records (e.g., chart notes, laboratory values) documenting inability of cross sex hormone therapy to inhibit natal secondary sex characteristics, luteinizing hormone (LH), or gonadotropins (e.g., menses, testosterone)

**AND**

**7** - Submission of medical records (e.g., chart notes, laboratory values) documenting a letter from the prescriber and/or formal documentation stating ALL of the following:

**7.1** Transgender patient continues to meet goals of gender-affirming hormone therapy

**AND**

**7.2** Coexisting psychiatric and medical comorbidities or social problems that may interfere with the diagnostic procedures or treatment continue to be addressed or removed

**AND**

**7.3** BOTH of the following:

**7.3.1** Current enrollment, attendance, and active participation in psychological and social support treatment program

**AND**

**7.3.2** Patient will continue enrollment, attendance, and active participation in psychological and social support throughout the course of treatment

**AND**

**7.4** Patient demonstrates knowledge and understanding of the expected outcomes of treatment and related transgender therapies

|       |                                                                        |
|-------|------------------------------------------------------------------------|
| Notes | *Please verify gender dysphoria is a coverable benefit for the patient |
|-------|------------------------------------------------------------------------|

Product Name:Lupron Depot, Lupron Depot-Ped, Fensolvi, Triptodur, leuprolide acetate inj kit 5 mg/mL, leuprolide acetate (3 month) 22.5 mg inj

|           |                        |
|-----------|------------------------|
| Diagnosis | Fertility Preservation |
|-----------|------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

### Approval Criteria

**1** - For use in pre-menopausal women

**AND**

**2** - Patient is receiving a cytotoxic agent that is associated with causing primary ovarian insufficiency (premature ovarian failure) [e.g., Cytosan (cyclophosphamide), procarbazine, vinblastine, cisplatin]

Product Name:Lupron Depot, Lupron Depot-Ped, Fensolvi, Triptodur, leuprolide acetate inj kit 5 mg/mL, leuprolide acetate (3 month) 22.5 mg inj

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                        |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Fertility Preservation |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 12 month(s)            |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Reauthorization        |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Prior Authorization    |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Patient is currently receiving gonadotropin-releasing hormone (GnRH) analog therapy for the purpose of fertility preservation</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Patient continues to receive a cytotoxic agent that is associated with causing primary ovarian insufficiency (premature ovarian failure) [e.g., Cytosan (cyclophosphamide), procarbazine, vinblastine, cisplatin]</p> |                        |

|                                                                                                                                                                                                          |                       |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:leuprolide acetate inj kit 5 mg/mL                                                                                                                                                          |                       |
| Diagnosis                                                                                                                                                                                                | Salivary Gland Tumors |
| Guideline Type                                                                                                                                                                                           | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - For a diagnosis of salivary gland tumors, the requested medication is not delegated to OptumRx for review and should be processed as a medical benefit</p> |                       |

|                                                 |                     |
|-------------------------------------------------|---------------------|
| Product Name:leuprolide acetate inj kit 5 mg/mL |                     |
| Diagnosis                                       | Uterine Sarcoma     |
| Guideline Type                                  | Prior Authorization |
| <p><b>Approval Criteria</b></p>                 |                     |

**1** - For a diagnosis of uterine sarcoma, the requested medication is not delegated to OptumRx for review and should be processed as a medical benefit

|                                                                                                                                                                                                                                                                       |                           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Lupron Depot, Lupron Depot-Ped, leuprolide acetate inj kit 5 mg/mL                                                                                                                                                                                       |                           |
| Diagnosis                                                                                                                                                                                                                                                             | NCCN Recommended Regimens |
| Guideline Type                                                                                                                                                                                                                                                        | Prior Authorization       |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - For uses supported by the National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, the requested medication is not delegated to OptumRx for review and should be processed as a medical benefit</p> |                           |

## 2 . Revision History

| Date       | Notes                                                                                                                     |
|------------|---------------------------------------------------------------------------------------------------------------------------|
| 11/26/2024 | Updated GPIs. Updated step therapy in CPP section as Fensolvi was moved to preferred and Lupron Depot Ped was moved to NP |

Growth Hormone, Growth Stimulating Agents



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-448315                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Guideline Name</b> | Growth Hormone, Growth Stimulating Agents                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 12/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                                                                                                                                                     |                                            |
|-----------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|
| Product Name: Genotropin, Genotropin Miniquick, Humatrope, Norditropin Flexpro, Nutropin AQ NuSpin, Omnitrope, Saizen, Zomacton, Zorbtive, Serostim |                                            |
| Diagnosis                                                                                                                                           | Congenital Growth Hormone Deficiency (GHD) |
| Approval Length                                                                                                                                     | 12 month(s)                                |
| Therapy Stage                                                                                                                                       | Initial Authorization                      |
| Guideline Type                                                                                                                                      | Prior Authorization                        |



### **Approval Criteria**

**1** - Infant is less than 12 months of age

**AND**

**2** - Submission of medical records documenting evidence of growth failure confirmed by all of the following:

- Growth charts for length/height and weight for age and gender with evidence of growth velocity deceleration over time
- Documentation of length/height and weight for age and gender including percentile and/or standard deviation scores
- Calculated growth velocity

**AND**

**3** - Submission of medical records documenting one of the following:

**3.1** Both of the following:

- Hypothalamic-pituitary defect (e.g., ectopic posterior pituitary, empty sella, hypoplastic pituitary, major congenital malformation, optic nerve hypoplasia, tumor or irradiation)
- Deficiency of at least one additional pituitary hormone

**OR**

**3.2** All of the following:

- Neonatal hypoglycemia and/or micropenis
- Serum GH (growth hormone) concentration less than or equal to 5 micrograms per liter in the first 28 days of life
- Deficiency of at least one additional pituitary hormone
- Classical imaging triad (i.e., ectopic posterior pituitary and pituitary hypoplasia with abnormal stalk)

**AND**

**4** - Submission of medical records documenting one of the following is below the age and gender adjusted normal range as provided by the physician's lab:

- Insulin-like Growth Factor 1 (IGF-1/Somatomedin-C)
- Insulin Growth Factor Binding Protein-3 (IGFBP-3)

**AND**

**5** - Prescribed by an endocrinologist

**AND**

**6** - Request does not exceed a maximum supply limit of 0.3 mg/kg/week (milligrams per kilogram per week)

**AND**

**7** - If the request is for a non-preferred medication, there must be a reason or special circumstance that the patient must be treated with a non-preferred medication\* (document reason or special circumstance)

|       |                                    |
|-------|------------------------------------|
| Notes | *See Table 1 in Background section |
|-------|------------------------------------|

|                                                                                                                                                                                                                                                                                                         |                                            |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|
| Product Name: Genotropin, Genotropin Miniquick, Humatrope, Norditropin Flexpro, Nutropin AQ NuSpin, Omnitrope, Saizen, Zomacton, Zorbtive, Serostim                                                                                                                                                     |                                            |
| Diagnosis                                                                                                                                                                                                                                                                                               | Congenital Growth Hormone Deficiency (GHD) |
| Approval Length                                                                                                                                                                                                                                                                                         | 12 month(s)                                |
| Therapy Stage                                                                                                                                                                                                                                                                                           | Reauthorization                            |
| Guideline Type                                                                                                                                                                                                                                                                                          | Prior Authorization                        |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Submission of medical records documenting a height increase of at least 2 centimeters per year over the previous year confirmed by all of the following:</p> <ul style="list-style-type: none"> <li>• Previous length/height and date obtained</li> </ul> |                                            |

- Current length/height and date obtained
- Calculated growth velocity
- Growth chart for length/height for age and gender

**AND**

**2** - Submission of medical records documenting both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal (e.g. genetic potential)

**AND**

**3** - Prescribed by an endocrinologist

**AND**

**4** - Request does not exceed a maximum supply limit of 0.3mg/kg/week (milligrams per kilogram per week)

Product Name: Genotropin, Genotropin Miniquick, Humatrope, Norditropin Flexpro, Nutropin AQ NuSpin, Omnitrope, Saizen, Zomacton, Zorbtive, Serostim, Ngenla, Skytrofa, Sogroya

|                 |                                            |
|-----------------|--------------------------------------------|
| Diagnosis       | Pediatric Growth Hormone Deficiency (GHD)* |
| Approval Length | 12 month(s)                                |
| Therapy Stage   | Initial Authorization                      |
| Guideline Type  | Prior Authorization                        |

### Approval Criteria

**1** - Submission of medical records documenting a diagnosis of pediatric GH (growth hormone) deficiency

**AND**

**2** - Submission of medical records documenting evidence of growth failure confirmed by all of the following:

- Growth charts for length/height and weight for age and gender with evidence of growth velocity deceleration over time
- Documentation of length/height and weight for age and gender including percentile and/or standard deviation scores
- Calculated growth velocity

**AND**

**3** - Submission of medical records documenting open epiphyses in the last 12 months

**AND**

**4** - Submission of medical records documenting Tanner stage less than or equal to 4

**AND**

**5** - Submission of medical records documenting both of the following:

**5.1** Patient has undergone two of the following provocative GH stimulation tests:

- Arginine
- Clonidine
- Glucagon
- Insulin
- Levodopa

**AND**

**5.2** Peak GH responses to each agent is less than 10 mcg/L (micrograms per liter)

**AND**

**6** - If patient has a history of malignancy, one of the following:

- Patient is in remission

- Patient has been stable for at least 12 months

**AND**

**7 - Prescribed by an endocrinologist**

**AND**

**8 - One of the following:**

**8.1** If the request is for Ngenla, request does not exceed a maximum supply limit of 0.66 mg/kg/week (milligrams per kilogram per week)

**OR**

**8.2** If the request is for any other product, one of the following:

**8.2.1** Request does not exceed a maximum supply limit of 0.3 mg/kg/week

**OR**

**8.2.2** All of the following:

**8.2.2.1** One of the following:

- Poor catch-up growth while on standard dosing
- IGF-1 (Insulin-like Growth Factor 1) less than 2 standard deviations from the mean while on standard dosing

**AND**

**8.2.2.2** Tanner Stage 2 or greater

**AND**

**8.2.2.3** Request does not exceed a maximum supply limit of 0.7 mg/kg/week

**AND**

**9** - One of the following:

**9.1** If the request is for a non-preferred somatropin medication, there must be a reason or special circumstance that the patient must be treated with a non-preferred medication\*\* (document reason or special circumstance)

**OR**

**9.2** If the request is for Sogroya, one of the following:

**9.2.1** Failure to one of the following, confirmed by claims history or submission of medical records:

- Somatropin (Norditropin)
- Somatropin (Omnitrope)

**OR**

**9.2.2** History of intolerance or contraindication to both of the following (please specify intolerance or contraindication):

- Somatropin (Norditropin)
- Somatropin (Omnitrope)

**OR**

**9.3** If the request is for Ngenla or Skytrofa, one of the following:

**9.3.1** Failure to both of the following, confirmed by claims history or submission of medical records:

- Somatropin (Norditropin or Omnitrope)
- Sogroya (somapacitan)

**OR**

**9.3.2** History of intolerance or contraindication to both of the following (please specify intolerance or contraindication):

- Somatropin (Norditropin or Omnitrope)
- Sogroya (somapacitan)

Notes

\*If patient is a Transition Phase Adolescent or Adult who had childhood onset GH deficiency, utilize criteria for Transition Phase Adolescent or Adult GH Deficiency.  
 \*\*See Table 1 in Background section

Product Name: Genotropin, Genotropin Miniquick, Humatrope, Norditropin Flexpro, Nutropin AQ NuSpin, Omnitrope, Saizen, Zomacton, Zorbtive, Serostim, Ngenla, Skytrofa, Sogroya

|                 |                                            |
|-----------------|--------------------------------------------|
| Diagnosis       | Pediatric Growth Hormone Deficiency (GHD)* |
| Approval Length | 12 month(s)                                |
| Therapy Stage   | Reauthorization                            |
| Guideline Type  | Prior Authorization                        |

### Approval Criteria

**1** - Submission of medical records documenting a height increase of at least 2 centimeters per year over the previous year confirmed by all of the following:

- Previous length/height and date obtained
- Current length/height and date obtained
- Calculated growth velocity
- Growth chart for length/height for age and gender

**AND**

**2** - Submission of medical records documenting both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal (e.g. genetic potential)

**AND**

**3** - Prescribed by an endocrinologist

**AND**

**4** - ONE of the following:

**4.1** If the request is for Ngenla, request does not exceed a maximum supply limit of 0.66 mg/kg/week (milligrams per kilogram per week)

**OR**

**4.2** If the request is for any other product, one of the following:

**4.2.1** Request does not exceed a maximum supply limit of 0.3 mg/kg/week

**OR**

**4.2.2** All of the following:

**4.2.2.1** One of the following:

- Poor catch-up growth while on standard dosing
- IGF-1 (Insulin-like Growth Factor 1) less than 2 standard deviations from the mean while on standard dosing

**AND**

**4.2.2.2** Tanner Stage 2 or greater

**AND**

**4.2.2.3** Request does not exceed a maximum supply limit of 0.7 mg/kg/week

|       |                                                                                                                                                                       |
|-------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Notes | *If patient is a Transition Phase Adolescent or Adult who had childhood onset GH deficiency, utilize criteria for Transition Phase Adolescent or Adult GH Deficiency. |
|-------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|



|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                       |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|
| Product Name: Genotropin, Genotropin Miniquick, Humatrope, Norditropin Flexpro, Nutropin AQ NuSpin, Omnitrope, Saizen, Zomacton, Zorbtive, Serostim                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                       |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Transition Phase Adolescent Patients* |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 12 month(s)                           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Initial Authorization                 |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Prior Authorization                   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Submission of medical records documenting one of the following:</p> <p><b>1.1</b> Genetic mutation</p> <p style="text-align: center;"><b>OR</b></p> <p><b>1.2</b> Deficiency of three of the following anterior pituitary hormones:</p> <ul style="list-style-type: none"> <li>• ACTH (adrenocorticotrophic hormone)</li> <li>• TSH (thyroid stimulating hormone)</li> <li>• Prolactin</li> <li>• FSH/LH (follicle-stimulating hormone/luteinizing hormone)</li> </ul> <p style="text-align: center;"><b>OR</b></p> <p><b>1.3</b> Irreversible structural hypothalamic-pituitary disease</p> <p style="text-align: center;"><b>OR</b></p> <p><b>1.4</b> Panhypopituitarism</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Submission of medical records documenting one of the following:</p> <p><b>2.1</b> IGF-1 (Insulin-like Growth Factor 1) level is below the age and gender adjusted normal range as provided by the physician's lab</p> |                                       |

**OR**

**2.2** Both of the following:

**2.2.1** Patient has undergone one of the following GH (growth hormone) stimulation tests after discontinuation of therapy for at least 1 month:

- Insulin tolerance test (ITT)
- GH-releasing hormone-arginine test (GHRH and ARG)
- Glucagon stimulation test (GST)
- Macimorelin

**AND**

**2.2.2** One of the following peak GH values:

- ITT less than or equal to 5.1 micrograms per liter
- GHRH and ARG less than or equal to 11 micrograms per liter
- Glucagon less than or equal to 3 micrograms per liter
- Macimorelin less than or equal to 2.8 ng/mL (nanograms per milliliter)

**AND**

**3** - Prescribed by an endocrinologist

**AND**

**4** - One of the following:

**4.1** Request does not exceed a maximum supply limit of 0.3mg/kg/week (milligrams per kilogram per week)

**OR**

**4.2** All of the following:

**4.2.1** One of the following:

- Poor catch-up growth while on standard dosing
- IGF-1 less than 2 standard deviations from the mean while on standard dosing

**AND**

**4.2.2** Tanner Stage 2 or greater

**AND**

**4.2.3** Request does not exceed a maximum supply limit of 0.7 mg/kg/week

**AND**

**5** - If the request is for a non-preferred medication, there must be a reason or special circumstance that the patient must be treated with a non-preferred medication\*\* (document reason or special circumstance)

|       |                                                                                                                                                                                                                                                                   |
|-------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Notes | <p>*Use this criteria for patients diagnosed with GHD in childhood during the transition period from puberty to adulthood (the period from mid to late teens until 6 to 7 years after achievement of adult height)</p> <p>**See Table 1 in Background section</p> |
|-------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                                                                                                                                                                                                                                                                                                  |                                       |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|
| Product Name: Genotropin, Genotropin Miniquick, Humatrope, Norditropin Flexpro, Nutropin AQ NuSpin, Omnitrope, Saizen, Zomacton, Zorbtive, Serostim                                                                                                                                              |                                       |
| Diagnosis                                                                                                                                                                                                                                                                                        | Transition Phase Adolescent Patients* |
| Approval Length                                                                                                                                                                                                                                                                                  | 12 month(s)                           |
| Therapy Stage                                                                                                                                                                                                                                                                                    | Reauthorization                       |
| Guideline Type                                                                                                                                                                                                                                                                                   | Prior Authorization                   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Submission of medical records documenting a positive response to therapy (e.g., increase in total lean body mass, exercise capacity or IGF-1 [Insulin-like Growth Factor 1] and IGFBP-3 [Insulin-like growth factor binding protein 3] levels)</p> |                                       |

**AND**

**2** - Prescribed by an endocrinologist

**AND**

**3** - One of the following:

**3.1** Request does not exceed a maximum supply limit of 0.3 mg/kg/week (milligrams per kilogram per week)

**OR**

**3.2** All of the following:

**3.2.1** One of the following:

- Poor catch-up growth while on standard dosing
- IGF-1 less than 2 standard deviations from the mean while on standard dosing

**AND**

**3.2.2** Tanner Stage 2 or greater

**AND**

**3.2.3** Request does not exceed a maximum supply limit of 0.7 mg/kg/week

|       |                                                                                                                                                                                                                 |
|-------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Notes | *Use this criteria for patients diagnosed with GHD in childhood during the transition period from puberty to adulthood (the period from mid to late teens until 6 to 7 years after achievement of adult height) |
|-------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                                                                                                                                                                        |                                 |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|
| Product Name: Genotropin, Genotropin Miniquick, Humatrope, Norditropin Flexpro, Nutropin AQ NuSpin, Omnitrope, Saizen, Zomacton, Zorbtive, Serostim, Skytrofa, Sogroya |                                 |
| Diagnosis                                                                                                                                                              | Adult Growth Hormone Deficiency |
| Approval Length                                                                                                                                                        | 12 month(s)                     |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                       |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Submission of medical records documenting a diagnosis of adult growth hormone deficiency (GHD) as a result of one of the following:</p> <ul style="list-style-type: none"> <li>• Known hypothalamic or pituitary disease</li> <li>• Panhypopituitarism</li> <li>• History of GHD in childhood</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Submission of medical records documenting one of the following:</p> <p><b>2.1</b> IGF-1 (Insulin-like Growth Factor 1) level is below the age and gender adjusted normal range as provided by the physician's lab</p> <p style="text-align: center;"><b>OR</b></p> <p><b>2.2</b> All of the following:</p> <p><b>2.2.1</b> Patient does not have a low IGF-1</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2.2.2</b> Patient has undergone one of the following GH (growth hormone) stimulation tests:</p> <ul style="list-style-type: none"> <li>• GH-releasing hormone-arginine test (GHRH and ARG)</li> <li>• Glucagon stimulation test (GST)</li> <li>• Macimorelin</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>2.2.3</b> One of the following peak GH values:</p> <ul style="list-style-type: none"> <li>• GHRH and ARG less than or equal to 11 micrograms per liter</li> </ul> |                       |

- Glucagon less than or equal to 3 ng/mL (nanograms per milliliter)
- Macimorelin less than or equal to 2.8 ng/mL

**AND**

**3 - ONE of the following:**

**3.1** Diagnosis of panhypopituitarism

**OR**

**3.2** Other diagnosis and not used in combination with the following:

- Aromatase inhibitors [e.g., Arimidex (anastrozole), Femara (letrozole)]
- Androgens [e.g., Delatestryl (testosterone enanthate), Depo-Testosterone (testosterone cypionate)]

**AND**

**4 - Prescribed by an endocrinologist**

**AND**

**5 - One of the following:**

**5.1** If the request is for a non-preferred somatropin medication, there must be a reason or special circumstance that the patient must be treated with a non-preferred medication\* (document reason or special circumstance)

**OR**

**5.2** If the request is for Sogroya, one of the following:

**5.2.1** Failure to one of the following, confirmed by claims history or submission of medical records:

- Somatropin (Norditropin)
- Somatropin (Omnitrope)

**OR**

**5.2.2** History of intolerance or contraindication to both of the following (please specify intolerance or contraindication):

- Somatropin (Norditropin)
- Somatropin (Omnitrope)

**OR**

**5.3** If the request is for Skytrofa, one of the following:

**5.3.1** Failure to both of the following, confirmed by claims history or submission of medical records:

- Somatropin (Norditropin or Omnitrope)
- Sogroya (somapacitan)

**OR**

**5.3.2** History of intolerance or contraindication to both of the following (please specify intolerance or contraindication):

- Somatropin (Norditropin or Omnitrope)
- Sogroya (somapacitan)

|       |                                    |
|-------|------------------------------------|
| Notes | *See Table 1 in Background section |
|-------|------------------------------------|

|                                                                                                                                                                        |                                 |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|
| Product Name: Genotropin, Genotropin Miniquick, Humatrope, Norditropin Flexpro, Nutropin AQ NuSpin, Omnitrope, Saizen, Zomacton, Zorbtive, Serostim, Skytrofa, Sogroya |                                 |
| Diagnosis                                                                                                                                                              | Adult Growth Hormone Deficiency |
| Approval Length                                                                                                                                                        | 12 month(s)                     |
| Therapy Stage                                                                                                                                                          | Reauthorization                 |
| Guideline Type                                                                                                                                                         | Prior Authorization             |
| <b>Approval Criteria</b>                                                                                                                                               |                                 |

**1** - Submission of medical records documenting an IGF-1 (Insulin-like Growth Factor 1) level within the past 12 months

**AND**

**2** - ONE of the following:

**2.1** Diagnosis of panhypopituitarism

**OR**

**2.2** Other diagnosis and not used in combination with the following:

- Aromatase inhibitors [e.g., Arimidex (anastrozole), Femara (letrozole)]
- Androgens [e.g., Delatestryl (testosterone enanthate), Depo-Testosterone (testosterone cypionate)]

**AND**

**3** - Prescribed by an endocrinologist

Product Name: Genotropin, Genotropin Miniquick, Humatrope, Norditropin Flexpro, Nutropin AQ NuSpin, Omnitrope, Saizen, Zomacton, Zorbtive, Serostim

|                 |                       |
|-----------------|-----------------------|
| Diagnosis       | Prader-Willi Syndrome |
| Approval Length | 12 month(s)           |
| Therapy Stage   | Initial Authorization |
| Guideline Type  | Prior Authorization   |

### Approval Criteria

**1** - Submission of medical records documenting both of the following:

**1.1** Diagnosis of Prader-Willi Syndrome



**AND**

**1.2** Diagnosis confirmed by genetic testing

**AND**

**2** - One of the following:

**2.1** Both of the following:

**2.1.1** Patient is less than 18 years of age

**AND**

**2.1.2** Submission of medical records documenting evidence of growth failure confirmed by all of the following:

- Growth charts for length/height and weight for age and gender with evidence of growth velocity deceleration over time
- Documentation of length/height and weight for age and gender including percentile and/or standard deviation scores
- Calculated growth velocity

**OR**

**2.2** Patient is greater than or equal to 18 years of age

**AND**

**3** - Patient does NOT have any one of the following:

- Active malignancy
- Severe obesity (weight greater than 225 percent of ideal body weight)
- Severe respiratory impairment

**AND**

**4** - Prescribed by ONE of the following:

- Endocrinologist
- Geneticist
- Specialist with knowledge in the treatment of Prader-Willi syndrome

**AND**

**5** - If the request is for a non-preferred medication, there must be a reason or special circumstance that the patient must be treated with a non-preferred medication\* (document reason or special circumstance)

Notes

\*See Table 1 in Background section

Product Name: Genotropin, Genotropin Miniquick, Humatrope, Norditropin Flexpro, Nutropin AQ NuSpin, Omnitrope, Saizen, Zomacton, Zorbtive, Serostim

Diagnosis Prader-Willi Syndrome

Approval Length 12 month(s)

Therapy Stage Reauthorization

Guideline Type Prior Authorization

### Approval Criteria

**1** - ONE of the following:

**1.1** All of the following:

**1.1.1** Patient is less than 18 years of age

**AND**

**1.1.2** Submission of medical records documenting a height increase of at least 2 centimeters per year over the previous year of treatment as confirmed by all of the following:

- Previous length/height and date obtained
- Current length/height and date obtained
- Calculated growth velocity

- Growth charts for length/height for age and gender

**AND**

**1.1.3** Submission of medical records documenting both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

**OR**

**1.2** Both of the following:

**1.2.1** Patient is greater than or equal to 18 years of age

**AND**

**1.2.2** Submission of medical records documenting a positive response to therapy (e.g., reduction in fat mass, increase in lean body mass, improved strength and exercise tolerance)

**AND**

**2** - Prescribed by ONE of the following:

- Endocrinologist
- Geneticist
- Specialist with knowledge in the treatment of Prader-Willi syndrome

Product Name: Genotropin, Genotropin Miniquick, Humatrope, Norditropin Flexpro, Nutropin AQ NuSpin, Omnitrope, Saizen, Zomacton, Zorbtive, Serostim

|                 |                                                            |
|-----------------|------------------------------------------------------------|
| Diagnosis       | Growth Failure in Children Small for Gestational Age (SGA) |
| Approval Length | 12 month(s)                                                |
| Therapy Stage   | Initial Authorization                                      |
| Guideline Type  | Prior Authorization                                        |

**Approval Criteria**

**1** - Submission of medical records documenting diagnosis of growth failure associated with SGA (small for gestational age)

**AND**

**2** - Submission of medical records documenting diagnosis has been confirmed by all of the following:

**2.1** Growth charts for length/height and weight for gestational age and gender at birth

**AND**

**2.2** Documentation that birth length/height and/or weight greater than or equal to 2 SD (standard deviations) below mean for gestational age

**AND**

**2.3** Infant growth charts for length/height and weight for age and gender between birth and 24 to 36 months of age do not show evidence of catch-up growth in length/height and/or weight (i.e., length/height or weight remained greater than or equal 2 SD below mean for age and gender from birth to age 2 to 3)

**AND**

**2.4** Documentation that current length/height and/or weight remains greater than or equal to 2 SD below mean for age and gender

**AND**

**2.5** Calculated growth velocity

**AND**

**3** - Prescribed by an endocrinologist

**AND**

**4** - If the request is for a non-preferred medication, there must be a reason or special circumstance that the patient must be treated with a non-preferred medication\* (document reason or special circumstance)

Notes

\*See Table 1 in Background section

Product Name: Genotropin, Genotropin Miniquick, Humatrope, Norditropin Flexpro, Nutropin AQ NuSpin, Omnitrope, Saizen, Zomacton, Zorbtive, Serostim

|                 |                                                            |
|-----------------|------------------------------------------------------------|
| Diagnosis       | Growth Failure in Children Small for Gestational Age (SGA) |
| Approval Length | 12 month(s)                                                |
| Therapy Stage   | Reauthorization                                            |
| Guideline Type  | Prior Authorization                                        |

### Approval Criteria

**1** - Submission of medical records documenting a height increase of at least 2 centimeters per year over the previous year confirmed by all of the following:

- Previous length/height and date obtained
- Current length/height and date obtained
- Calculated growth velocity
- Growth chart for length/height for age and gender

**AND**

**2** - Submission of medical records documenting both of the following:

- Expected adult height not attained
- Expected adult height goal

**AND**

**3 - Prescribed by an endocrinologist**

Product Name: Genotropin, Genotropin Miniquick, Humatrope, Norditropin Flexpro, Nutropin AQ NuSpin, Omnitrope, Saizen, Zomacton, Zorbtive, Serostim

|                 |                                    |
|-----------------|------------------------------------|
| Diagnosis       | Turner Syndrome or Noonan Syndrome |
| Approval Length | 12 month(s)                        |
| Therapy Stage   | Initial Authorization              |
| Guideline Type  | Prior Authorization                |

**Approval Criteria**

**1 - Submission of medical records documenting one of the following:**

**1.1 BOTH of the following:**

**1.1.1** Diagnosis of Turner Syndrome

**AND**

**1.1.2** Diagnosis confirmed by genetic testing

**OR**

**1.2 BOTH of the following:**

**1.2.1** Diagnosis of Noonan Syndrome

**AND**

**1.2.2** Diagnosis confirmed by the presence of clinical features consistent with Noonan Syndrome (e.g., distinct facial features such as high forehead, hypertelorism, down slanting palpebral fissures with high arched eyebrows, epicanthic folds, full upper lip with a depressed nasal bridge, low set ears, blue irises, ptosis and neck webbing, pulmonary valve stenosis, hypertrophic cardiomyopathy, pectus carinatum/excavatum, mild developmental delay, cryptorchidism, lymphatic dysplasia)

**AND**

**2** - Submission of medical records documenting all of the following:

- Growth charts for length/height and weight for age and gender with evidence of growth velocity deceleration over time
- Documentation of length/height and weight for age and gender including percentile and/or standard deviation score
- Calculated growth velocity

**AND**

**3** - Submission of medical records documenting open epiphyses in the last 12 months

**AND**

**4** - Submission of medical records documenting Tanner staging less than or equal to 4

**AND**

**5** - Prescribed by an endocrinologist

**AND**

**6** - If the request is for a non-preferred medication, there must be a reason or special circumstance that the patient must be treated with a non-preferred medication\* (document reason or special circumstance)

Notes

\*See Table 1 in Background section

Product Name: Genotropin, Genotropin Miniquick, Humatrope, Norditropin Flexpro, Nutropin AQ NuSpin, Omnitrope, Saizen, Zomacton, Zorbtive, Serostim

|                 |                                    |
|-----------------|------------------------------------|
| Diagnosis       | Turner Syndrome or Noonan Syndrome |
| Approval Length | 12 month(s)                        |
| Therapy Stage   | Reauthorization                    |

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Prior Authorization |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Submission of medical records documenting a height increase of at least 2 centimeters per year over the previous year confirmed by all of the following:</p> <ul style="list-style-type: none"> <li>• Previous length/height and date obtained</li> <li>• Current length/height and date obtained</li> <li>• Calculated growth velocity</li> <li>• Growth chart for height for age and gender</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Submission of medical records documenting both of the following:</p> <ul style="list-style-type: none"> <li>• Expected adult height not attained</li> <li>• Expected adult height goal</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Prescribed by an endocrinologist</p> |                     |

|                                                                                                                                                                                                 |                                               |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|
| Product Name: Genotropin, Genotropin Miniquick, Humatrope, Norditropin Flexpro, Nutropin AQ NuSpin, Omnitrope, Saizen, Zomacton, Zorbtive, Serostim                                             |                                               |
| Diagnosis                                                                                                                                                                                       | Short-Stature Homeobox (SHOX) Gene Deficiency |
| Approval Length                                                                                                                                                                                 | 12 month(s)                                   |
| Therapy Stage                                                                                                                                                                                   | Initial Authorization                         |
| Guideline Type                                                                                                                                                                                  | Prior Authorization                           |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Submission of medical records documenting both of the following:</p> <p><b>1.1</b> Diagnosis of short-stature homeobox (SHOX) gene deficiency</p> |                                               |



**AND**

**1.2** Diagnosis confirmed by genetic testing

**AND**

**2** - Submission of medical records documenting all of the following:

- Growth charts for length/height and weight for age and gender with evidence of growth velocity deceleration over time
- Documentation of length/height and weight for age and gender including percentile and/or standard deviation scores
- Calculated growth velocity

**AND**

**3** - Submission of medical records documenting open epiphyses in the last 12 months

**AND**

**4** - Submission of medical records documenting Tanner stage less than or equal to 4

**AND**

**5** - Prescribed by an endocrinologist

**AND**

**6** - If the request is for a non-preferred medication, there must be a reason or special circumstance that the patient must be treated with a non-preferred medication\* (document reason or special circumstance)

Notes

\*See Table 1 in Background section

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                               |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|
| Product Name: Genotropin, Genotropin Miniquick, Humatrope, Norditropin Flexpro, Nutropin AQ NuSpin, Omnitrope, Saizen, Zomacton, Zorbtive, Serostim                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                               |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Short-Stature Homeobox (SHOX) Gene Deficiency |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | 12 month(s)                                   |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Reauthorization                               |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Prior Authorization                           |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Submission of medical records documenting a height increase of at least 2 centimeters per year over the previous year confirmed by all of the following:</p> <ul style="list-style-type: none"> <li>• Previous length/height and date obtained</li> <li>• Current length/height and date obtained</li> <li>• Calculated growth velocity</li> <li>• Growth chart for height for age and gender</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Submission of medical records documenting both of the following:</p> <ul style="list-style-type: none"> <li>• Expected adult height not attained</li> <li>• Expected adult height goal</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Prescribed by an endocrinologist</p> |                                               |

|                                                                                                                                                     |                                                            |
|-----------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------|
| Product Name: Genotropin, Genotropin Miniquick, Humatrope, Norditropin Flexpro, Nutropin AQ NuSpin, Omnitrope, Saizen, Zomacton, Zorbtive, Serostim |                                                            |
| Diagnosis                                                                                                                                           | Growth Failure associated with Chronic Renal Insufficiency |
| Approval Length                                                                                                                                     | 12 month(s)                                                |
| Therapy Stage                                                                                                                                       | Initial Authorization                                      |
| Guideline Type                                                                                                                                      | Prior Authorization                                        |

### **Approval Criteria**

**1** - Submission of medical records documenting all of the following:

**1.1** Diagnosis of chronic renal insufficiency

**AND**

**1.2** Documentation of all of the following:

- Growth charts for length/height and weight for age and gender with evidence of growth velocity deceleration over time
- Documentation of length/height and weight for age and gender including percentile and/or standard deviation scores
- Calculated growth velocity

**AND**

**1.3** Documentation of open epiphyses in the last 12 months

**AND**

**1.4** Tanner stage less than or equal to 4

**AND**

**2** - Patient has not yet had a renal transplant

**AND**

**3** - Prescribed by ONE of the following:

- Endocrinologist
- Nephrologist

**AND**

**4** - If the request is for a non-preferred medication, there must be a reason or special circumstance that the patient must be treated with a non-preferred medication\* (document reason or special circumstance)

Notes

\*See Table 1 in Background section

Product Name: Genotropin, Genotropin Miniquick, Humatrope, Norditropin Flexpro, Nutropin AQ NuSpin, Omnitrope, Saizen, Zomacton, Zorbtive, Serostim

|           |                                                            |
|-----------|------------------------------------------------------------|
| Diagnosis | Growth Failure associated with Chronic Renal Insufficiency |
|-----------|------------------------------------------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                 |
|---------------|-----------------|
| Therapy Stage | Reauthorization |
|---------------|-----------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

### Approval Criteria

**1** - Submission of medical records documenting a height increase of at least 2 centimeters per year over the previous year confirmed by all of the following:

- Previous length/height and date obtained
- Current length/height and date obtained
- Calculated growth velocity
- Growth chart for height for age and gender

**AND**

**2** - Submission of medical records documenting of both of the following:

- Expected adult height not attained
- Expected adult height goal

**AND**

**3** - Patient has not yet had a renal transplant

**AND**

**4** - Prescribed by ONE of the following:

- Endocrinologist
- Nephrologist

**Product Name:** Serostim

|                 |                                                                            |
|-----------------|----------------------------------------------------------------------------|
| Diagnosis       | Human Immunodeficiency Virus (HIV)-associated wasting syndrome or cachexia |
| Approval Length | 3 month(s)                                                                 |
| Therapy Stage   | Initial Authorization                                                      |
| Guideline Type  | Prior Authorization                                                        |

**Approval Criteria**

**1** - Submission of medical records documenting all of the following:

**1.1** Diagnosis of HIV (human immunodeficiency virus)-associated wasting syndrome or cachexia

**AND**

**1.2** Involuntary weight loss of greater than 10 percent

**AND**

**1.3** One of the following:

**1.3.1** Chronic diarrhea (2 loose stools daily for more than 30 days)

**OR**

**1.3.2 Both of the following:**

- Chronic weakness
- Fever

**AND**

**1.4 Symptoms lasting greater than or equal to 30 days (intermittent or constant)**

**AND**

**1.5 Absence of a concurrent condition other than HIV infection that may cause these findings (e.g., depression, mycobacterium avium complex, chronic infectious diarrhea, or malignancy except for Kaposi's sarcoma limited to skin or mucous membranes)**

**AND**

**1.6 A nutritional evaluation has been completed since onset of wasting first occurred**

**AND**

**1.7 Patient's anti-retroviral therapy has been optimized to decrease the viral load**

|                                                                                                                    |                                                                            |
|--------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------|
| <b>Product Name: Serostim</b>                                                                                      |                                                                            |
| <b>Diagnosis</b>                                                                                                   | Human Immunodeficiency Virus (HIV)-associated wasting syndrome or cachexia |
| <b>Approval Length</b>                                                                                             | 6 month(s)                                                                 |
| <b>Therapy Stage</b>                                                                                               | Reauthorization                                                            |
| <b>Guideline Type</b>                                                                                              | Prior Authorization                                                        |
| <p><b>Approval Criteria</b></p> <p><b>1 - Submission of medical records documenting both of the following:</b></p> |                                                                            |

**1.1** Documentation of a positive response to therapy (i.e., greater than or equal to 2 percent increase in body weight and/or body cell mass)

**AND**

**1.2** One of the following targets or goals has not been achieved:

- Weight
- Body cell mass (BCM)
- Body mass index (BMI)

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                       |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------|
| Product Name: Zorbtive                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                       |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Short Bowel Syndrome                                                                                                                  |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                     | *4 weeks                                                                                                                              |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Prior Authorization                                                                                                                   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Submission of medical records documenting all of the following:</p> <p><b>1.1</b> Diagnosis of Short Bowel Syndrome</p> <p><b>AND</b></p> <p><b>1.2</b> Patient is currently receiving specialized nutritional support (e.g., intravenous parenteral nutrition, fluid, and micronutrient supplements)</p> <p><b>AND</b></p> <p><b>1.3</b> Patient has not previously received 4 weeks of treatment with Zorbtive*</p> |                                                                                                                                       |
| Notes                                                                                                                                                                                                                                                                                                                                                                                                                                                               | *Treatment with Zorbtive will not be authorized beyond 4 weeks. Administration for more than 4 weeks has not been adequately studied. |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------|
| Product Name:Increlex                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Severe Primary IGF-1 Deficiency / Growth Hormone Gene Deletion |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 12 month(s)                                                    |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Initial Authorization                                          |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Prior Authorization                                            |
| <p><b>Approval Criteria</b></p> <p>1 - Submission of medical records documenting all of the following:</p> <p>1.1 Diagnosis of severe primary IGF-1 deficiency (PIGFD)</p> <p style="text-align: center;"><b>AND</b></p> <p>1.2 Documentation of height below -3.0 SD (standard deviation) mean for age and gender</p> <p style="text-align: center;"><b>AND</b></p> <p>1.3 Documentation of IGF-1 below -3.0 SD mean for age and gender</p> <p style="text-align: center;"><b>AND</b></p> <p>1.4 Documentation of both of the following:</p> <ul style="list-style-type: none"> <li>• Growth charts for length/height and weight for age and gender with evidence of growth velocity deceleration over time</li> <li>• Calculated growth velocity</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p>1.5 One of the following:</p> <p>1.5.1 Patient is unresponsive to a trial of growth hormone therapy</p> |                                                                |



**OR**

**1.5.2** Documentation of one of the following:

- Very low or undetectable level of GHBP (growth hormone-binding protein)
- Very low or undetectable level of GHR (growth hormone receptor) mutations known to cause Laron syndrome/GH insensitivity syndrome
- GH1 gene deletion (GHD type 1A)
- GH-neutralizing antibodies
- STT5b gene mutation
- IGF-1 gene deletion or mutation

**AND**

**2** - Other causes of low IGF-I levels have been ruled out (e.g., growth hormone deficiency, undernutrition, hepatic disease)

**AND**

**3** - Patient will not be treated with concurrent growth hormone therapy

**AND**

**4** - Prescribed by an endocrinologist

|                          |                                                                |
|--------------------------|----------------------------------------------------------------|
| Product Name:Increlex    |                                                                |
| Diagnosis                | Severe Primary IGF-1 Deficiency / Growth Hormone Gene Deletion |
| Approval Length          | 12 month(s)                                                    |
| Therapy Stage            | Reauthorization                                                |
| Guideline Type           | Prior Authorization                                            |
| <b>Approval Criteria</b> |                                                                |

**1** - Submission of medical records documenting a height increase of at least 2 centimeters per year over the previous year of treatment as confirmed by all of the following:

- Previous length/height and date obtained
- Current length/height and date obtained
- Calculated growth velocity
- Growth chart for height for age and gender

**AND**

**2** - Submission of medical records documenting both of the following:

- Expected adult height not obtained
- Expected adult height goal

**AND**

**3** - Patient is not treated with concurrent growth hormone therapy

**AND**

**4** - Prescribed by an endocrinologist

## 2 . Background

### Benefit/Coverage/Program Information

#### Table 1: Human Growth Hormone:

##### Preferred Agents:

- Somatropin (Norditropin)
- Somatropin (Omnitrope)
- Sogroya (somapacitan)

**Nonpreferred Agents:**

- Somatropin (Genotropin, Humatrope, Nutropin AQ NuSpin, Saizen, Zorbtive, Serostim, and Zomacton)
- Skytrofa (lonapegsomatropin-tcgd)
- Ngenla (somatrogen)

**Growth Stimulating Products:**

- Mecasermin (Increlex)

### 3 . Revision History

| Date       | Notes                                                                                                                                                             |
|------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 11/19/2025 | Updated initial auth criteria for pediatric GHD and added adult GHD as covered indication for Skytrofa. Updated initial auth criteria for SGA . Updated GPI list. |

Haegarda



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-242196                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Guideline Name</b> | Haegarda                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 6/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                       |                       |
|-----------------------|-----------------------|
| Product Name:Haegarda |                       |
| Approval Length       | 12 month(s)           |
| Therapy Stage         | Initial Authorization |
| Guideline Type        | Prior Authorization   |

## **Approval Criteria**

**1** - Diagnosis of hereditary angioedema (HAE) as confirmed by ONE of the following:

**1.1** C1 inhibitor (C1-INH) deficiency or dysfunction (Type I or II HAE) as documented by ONE of the following (per laboratory standard):

- C1-INH antigenic level below the lower limit of normal
- C1-INH functional level below the lower limit of normal

**OR**

**1.2** HAE with normal C1 inhibitor levels and ONE of the following:

- Confirmed presence of variant(s) in the gene(s) for factor XII, angiotensin-converting enzyme 1, plasminogen-1, kininogen-1, myoferlin, and heparan sulfate-glucosaminase 3-O-sulfotransferase 6
- Recurring angioedema attacks that are refractory to high-dose antihistamines with confirmed family history of angioedema
- Recurring angioedema attacks that are refractory to high-dose antihistamines with unknown background de-novo mutation(s) (i.e., no family history) (HAE-unknown)

**AND**

**2** - Prescribed for the prophylaxis of HAE attacks

**AND**

**3** - Not used in combination with other products indicated for prophylaxis against HAE attacks (e.g., Cinryze, Orladeyo, Takhzyro)

**AND**

**4** - Prescriber attests that patient has experienced attacks of a severity and/or frequency such that they would clinically benefit from prophylactic therapy with Haegarda

**AND**

**5** - Prescribed by ONE of the following:

- Immunologist
- Allergist

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                     |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Haegarda                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                     |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 12 month(s)         |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of positive clinical response to Haegarda therapy</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Reduction in the utilization of on-demand therapies used for acute attacks (e.g., Berinert, Firazyr, Ruconest) as determined by claims information, while on Haegarda therapy</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Prescribed for the prophylaxis of HAE attacks</p> <p style="text-align: center;"><b>AND</b></p> <p><b>4</b> - Not used in combination with other products indicated for prophylaxis against HAE attacks (e.g., Cinryze, Orladeyo, Takhzyro)</p> <p style="text-align: center;"><b>AND</b></p> |                     |

**5** - Prescribed by ONE of the following:

- Immunologist
- Allergist

## **2 . Revision History**

| Date      | Notes                                        |
|-----------|----------------------------------------------|
| 4/17/2025 | Updated formularies. Minor formatting change |

HCG



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-145852                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Guideline Name</b> | HCG                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 5/1/2024 |
|-----------------|----------|

## 1 . Criteria

|                                                                |                            |
|----------------------------------------------------------------|----------------------------|
| Product Name:Novarel, Chorionic Gonadotropin, Ovidrel, Pregnyl |                            |
| Diagnosis                                                      | Prepubertal Cryptorchidism |
| Approval Length                                                | 6 Week(s)                  |
| Guideline Type                                                 | Prior Authorization        |
| Approval Criteria                                              |                            |



1 - Diagnosis of prepubertal cryptorchidism not due to anatomical obstruction

## 2 . Revision History

| Date      | Notes                |
|-----------|----------------------|
| 4/17/2024 | Removed MD formulary |

Hemangeol



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-164950                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Guideline Name</b> | Hemangeol                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 3/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                        |                     |
|------------------------|---------------------|
| Product Name:Hemangeol |                     |
| Approval Length        | 12 month(s)         |
| Guideline Type         | Prior Authorization |
| Approval Criteria      |                     |

**1** - Diagnosis of proliferating infantile hemangioma

**AND**

**2** - Prescriber provides a reason or special circumstance the patient cannot use generic propranolol oral solution

## **2 . Revision History**

| Date      | Notes               |
|-----------|---------------------|
| 2/10/2025 | Updated formularies |

Hemlibra



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-406205                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Guideline Name</b> | Hemlibra                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 11/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                       |                              |
|-----------------------|------------------------------|
| Product Name:Hemlibra |                              |
| Diagnosis             | Hemophilia A with Inhibitors |
| Approval Length       | 12 month(s)                  |
| Therapy Stage         | Initial Authorization        |
| Guideline Type        | Prior Authorization          |

**Approval Criteria**

1 - Diagnosis of hemophilia A

**AND**

2 - Patient has developed high-titer factor VIII inhibitors (i.e., patient has developed factor VIII inhibitors greater than or equal to 5 Bethesda units [BU])

**AND**

3 - Prescribed for the prevention of bleeding episodes (i.e., routine prophylaxis)

Product Name:Hemlibra

|           |                              |
|-----------|------------------------------|
| Diagnosis | Hemophilia A with Inhibitors |
|-----------|------------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                 |
|---------------|-----------------|
| Therapy Stage | Reauthorization |
|---------------|-----------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

1 - Documentation of positive clinical response to Hemlibra therapy

Product Name:Hemlibra

|           |                                 |
|-----------|---------------------------------|
| Diagnosis | Hemophilia A without Inhibitors |
|-----------|---------------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

**1** - Diagnosis of hemophilia A

**AND**

**2** - Patient has not developed high-titer factor VIII inhibitors (i.e., patient has NOT developed factor VIII inhibitors greater than or equal to 5 Bethesda units [BU])

**AND**

**3** - Prescribed for the prevention of bleeding episodes (i.e., routine prophylaxis)

Product Name:Hemlibra

|           |                                 |
|-----------|---------------------------------|
| Diagnosis | Hemophilia A without Inhibitors |
|-----------|---------------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                 |
|---------------|-----------------|
| Therapy Stage | Reauthorization |
|---------------|-----------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

**1** - Documentation of positive clinical response to Hemlibra therapy

## 2 . Revision History

| Date      | Notes                                                                                                                                                       |
|-----------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 9/29/2025 | Removed criteria of failure to meet clinical goals after a trial of prophylactic factor VIII replacement products. Clarified high titer inhibitor criteria. |

Hepatitis C Criteria



## Prior Authorization Guideline

|                       |                                                                                                         |
|-----------------------|---------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-147777                                                                                               |
| <b>Guideline Name</b> | Hepatitis C Criteria                                                                                    |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>Medicaid - Community &amp; State New Jersey (PSI2300)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 7/1/2024 |
|-----------------|----------|

## 1 . Criteria

|                                                                                                                                                                                                                                  |                          |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|
| Product Name:Mavyret                                                                                                                                                                                                             |                          |
| Diagnosis                                                                                                                                                                                                                        | Treatment Naive Patients |
| Guideline Type                                                                                                                                                                                                                   | Prior Authorization      |
| <p><b>Approval Criteria</b></p> <p>1 - Patient has a confirmed diagnosis of hepatitis C</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - The requested medication is age-appropriate according to FDA (Food and Drug</p> |                          |

Administration)-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

**AND**

**3** - One of the following:

**3.1** The patient is a kidney transplant recipient, authorization approval length is 12 weeks

**OR**

**3.2** The patient is not a kidney transplant recipient, authorization approval length is 8 weeks

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|
| Product Name:Mavyret                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Treatment Experienced Patients |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Prior Authorization            |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - The requested medication is age-appropriate according to FDA (Food and Drug Administration)-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature</p> <p><b>AND</b></p> <p><b>2</b> - Diagnosis of chronic hepatitis C virus (HCV) with labs showing genotype and detectable HCV RNA (ribonucleic acid) levels from within the past 90 days</p> <p><b>AND</b></p> <p><b>3</b> - BOTH of the following must be provided:</p> <ul style="list-style-type: none"> <li>• Previous treatment history including medication name(s) and length of therapy</li> <li>• Whether patient is a relapser, null responder, partial responder or non-compliant</li> </ul> |                                |



**AND**

**4** - Patient has been educated on the importance of compliance with their treatment regimen

**AND**

**5** - All of the following:

**5.1** Patient does not have contraindications to the requested Hepatitis C therapy

**AND**

**5.2** Patient is not on any therapies identified by the prescribing information or American Association for the Study of Liver Diseases/Infectious Diseases Society of America (AASLD/IDSA) guidelines as therapies not recommended for co-administration

**AND**

**5.3** Patient does not have limited life expectancy (< 12 months due to non-liver related comorbidities)

**AND**

**6** - If combined with ribavirin, patient will meet ALL of the following:

**6.1** Patient has no contraindication to ribavirin

**AND**

**6.2** Neither the patient nor the partner of the patient is pregnant

**AND**

**6.3** If the patient or their partner is of child bearing age, the patient has been or will be

instructed to practice effective contraception during therapy and for 6 months after stopping ribavirin therapy

**AND**

**7** - For patients with decompensated cirrhosis, the requested drug(s) must be prescribed by or in consultation with a liver transplant specialist

**AND**

**8** - Prior to treatment, patient has been assessed for HBV coinfection (e.g., HBsAG, anti-HBc), copy of lab work must be received

**AND**

**9** - For regimens that depend on testing [e.g., baseline high fold-change NS5A (nonstructural protein 5A) RASs (resistance-associated substitutions) (includes G1a polymorphisms at amino acid positions 28, 30, 31, or 93), baseline Q80K polymorphism, Y93H mutation], a copy of the lab work must be received

**AND**

**10** - Patient is genotype 1,2,3,4,5, or 6

**AND**

**11** - Patient is NOT receiving the requested medication in combination with another HCV direct acting antiviral agent [e.g., Epclusa (sofosbuvir/velpatasvir), Harvoni (ledipasvir/sofosbuvir), Sovaldi (sofosbuvir), Zepatier (elbasvir/grazoprevir)]

**AND**

**12** - The regimen is an approvable regimen, based on patient genotype and characteristics (see Table 1 in Background section)

|       |                                                                                         |
|-------|-----------------------------------------------------------------------------------------|
| Notes | Approval length is by regimen based on patient genotype and characteristics in Table 1. |
|-------|-----------------------------------------------------------------------------------------|

|                                                                                                                                                                                                                                                                                                                                                  |                          |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|
| Product Name:sofosbuvir/velpatasvir (authorized generic of Epclusa)                                                                                                                                                                                                                                                                              |                          |
| Diagnosis                                                                                                                                                                                                                                                                                                                                        | Treatment Naive Patients |
| Approval Length                                                                                                                                                                                                                                                                                                                                  | 12 Week(s)               |
| Guideline Type                                                                                                                                                                                                                                                                                                                                   | Prior Authorization      |
| <p><b>Approval Criteria</b></p> <p>1 - Patient has a confirmed diagnosis of hepatitis C</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - The requested medication is age-appropriate according to FDA (Food and Drug Administration)-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature</p> |                          |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|
| Product Name:sofosbuvir/velpatasvir (authorized generic of Epclusa)                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Treatment Experienced Patients |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Prior Authorization            |
| <p><b>Approval Criteria</b></p> <p>1 - The requested medication is age-appropriate according to FDA (Food and Drug Administration)-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Diagnosis of chronic hepatitis C virus (HCV) with labs showing genotype and detectable HCV RNA (ribonucleic acid) levels from within the past 90 days</p> <p style="text-align: center;"><b>AND</b></p> |                                |

**3 - BOTH of the following must be provided:**

- Previous treatment history including medication name(s) and length of therapy
- Whether patient is a relapser, null responder, partial responder or non-compliant

**AND**

**4 - Patient has been educated on the importance of compliance with their treatment regimen**

**AND**

**5 - All of the following:**

**5.1 Patient does not have contraindications to the requested Hepatitis C therapy**

**AND**

**5.2 Patient is not on any therapies identified by the prescribing information or American Association for the Study of Liver Diseases/Infectious Diseases Society of America (AASLD/IDSA) guidelines as therapies not recommended for co-administration**

**AND**

**5.3 Patient does not have limited life expectancy (< 12 months due to non-liver related comorbidities)**

**AND**

**6 - If combined with ribavirin, patient will meet ALL of the following:**

**6.1 Patient has no contraindication to ribavirin**

**AND**

**6.2 Neither the patient nor the partner of the patient is pregnant**

**AND**

**6.3** If the patient or their partner is of child bearing age, the patient has been or will be instructed to practice effective contraception during therapy and for 6 months after stopping ribavirin therapy

**AND**

**7** - For patients with decompensated cirrhosis, the requested drug(s) must be prescribed by or in consultation with a liver transplant specialist

**AND**

**8** - Prior to treatment, patient has been assessed for HBV coinfection (e.g., HBsAG, anti-HBc), copy of lab work must be received

**AND**

**9** - For regimens that depend on testing [e.g., baseline high fold-change NS5A (nonstructural protein 5A) RASs (resistance-associated substitutions) (includes G1a polymorphisms at amino acid positions 28, 30, 31, or 93), baseline Q80K polymorphism, Y93H mutation], a copy of the lab work must be received

**AND**

**10** - Patient is NOT receiving the requested medication in combination with another HCV direct acting antiviral agent [e.g., Epclusa, Harvoni (ledipasvir/sofosbuvir), Mavyret (glecaprevir/pibrentasvir), Sovaldi (sofosbuvir), Zepatier (elbasvir/grazoprevir)]

**AND**

**11** - The regimen is an approvable regimen, based on patient genotype and characteristics (see Table 2 in Background section)

Notes

Approval length is by regimen based on patient genotype and characteristics in Table 2.

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                          |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|
| Product Name:Zepatier                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                          |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Treatment Naive patients |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Prior Authorization      |
| <p><b>Approval Criteria</b></p> <p>1 - Patient has a confirmed diagnosis of hepatitis C</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - The requested medication is age-appropriate according to FDA (Food and Drug Administration)-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature</p> <p style="text-align: center;"><b>AND</b></p> <p>3 - One of the following:</p> <p>3.1 The patient is also requesting ribavirin, authorization approval length is 16 weeks</p> <p style="text-align: center;"><b>OR</b></p> <p>3.2 The patient is NOT also requesting ribavirin, authorization approval length is 12 weeks</p> |                          |

|                                                                                                                        |                                |
|------------------------------------------------------------------------------------------------------------------------|--------------------------------|
| Product Name:Zepatier                                                                                                  |                                |
| Diagnosis                                                                                                              | Treatment Experienced Patients |
| Guideline Type                                                                                                         | Prior Authorization            |
| <p><b>Approval Criteria</b></p> <p>1 - The requested medication is age-appropriate according to FDA (Food and Drug</p> |                                |

Administration)-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

**AND**

**2** - Diagnosis of chronic hepatitis C virus (HCV) with labs showing genotype and detectable HCV RNA (ribonucleic acid) levels from within the past 90 days

**AND**

**3** - BOTH of the following must be provided:

- Previous treatment history including medication name(s) and length of therapy
- Whether patient is a relapser, null responder, partial responder or non-compliant

**AND**

**4** - Patient has been educated on the importance of compliance with their treatment regimen

**AND**

**5** - All of the following:

**5.1** Patient does not have contraindications to the requested Hepatitis C therapy

**AND**

**5.2** Patient is not on any therapies identified by the prescribing information or American Association for the Study of Liver Diseases/Infectious Diseases Society of America (AASLD/IDSA) guidelines as therapies not recommended for co-administration

**AND**

**5.3** Patient does not have limited life expectancy (< 12 months due to non-liver related comorbidities)

**AND**

**6** - If combined with ribavirin, patient will meet ALL of the following:

**6.1** Patient has no contraindication to ribavirin

**AND**

**6.2** Neither the patient nor the partner of the patient is pregnant

**AND**

**6.3** If the patient or their partner is of child bearing age, the patient has been or will be instructed to practice effective contraception during therapy and for 6 months after stopping ribavirin therapy

**AND**

**7** - For patients with decompensated cirrhosis, the requested drug(s) must be prescribed by or in consultation with a liver transplant specialist

**AND**

**8** - Prior to treatment, patient has been assessed for HBV coinfection (e.g., HBsAG, anti-HBc), copy of lab work must be received

**AND**

**9** - For regimens that depend on testing [e.g., baseline high fold-change NS5A (nonstructural protein 5A) RASs (resistance-associated substitutions) (includes G1a polymorphisms at amino acid positions 28, 30, 31, or 93), baseline Q80K polymorphism, Y93H mutation], a copy of the lab work must be received

**AND**



**10** - Patient is NOT receiving the requested medication in combination with another HCV direct acting antiviral agent [e.g., Epclusa (sofosbuvir/velpatasvir), Harvoni (ledipasvir/sofosbuvir), Mavyret (glecaprevir/pibrentasvir), Sovaldi (sofosbuvir)]

**AND**

**11** - The regimen is an approvable regimen, based on patient genotype and characteristics (see Table 3 in Background section)

|       |                                                                                         |
|-------|-----------------------------------------------------------------------------------------|
| Notes | Approval length is by regimen based on patient genotype and characteristics in Table 3. |
|-------|-----------------------------------------------------------------------------------------|

Product Name: Brand Epclusa

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

### Approval Criteria

**1** - The requested medication is age-appropriate according to FDA (Food and Drug Administration)-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

**AND**

**2** - Diagnosis of chronic hepatitis C virus (HCV) with labs showing genotype and detectable HCV RNA (ribonucleic acid) levels from within the past 90 days

**AND**

**3** - For treatment-experienced patients, BOTH of the following must be provided:

- Previous treatment history including medication name(s) and length of therapy
- Whether patient is a relapser, null responder, partial responder or non-compliant

**AND**

**4** - Patient has been educated on the importance of compliance with their treatment regimen

**AND**

**5** - All of the following:

**5.1** Patient does not have contraindications to the requested Hepatitis C therapy

**AND**

**5.2** Patient is not on any therapies identified by the prescribing information or American Association for the Study of Liver Diseases/Infectious Diseases Society of America (AASLD/IDSA) guidelines as therapies not recommended for co-administration

**AND**

**5.3** Patient does not have limited life expectancy (< 12 months due to non-liver related comorbidities)

**AND**

**6** - If combined with ribavirin, patient will meet ALL of the following:

**6.1** Patient has no contraindication to ribavirin

**AND**

**6.2** Neither the patient nor the partner of the patient is pregnant

**AND**

**6.3** If the patient or their partner is of child bearing age, the patient has been or will be instructed to practice effective contraception during therapy and for 6 months after stopping ribavirin therapy

**AND**

**7** - For patients with decompensated cirrhosis, the requested drug(s) must be prescribed by or in consultation with a liver transplant specialist

**AND**

**8** - Prior to treatment, patient has been assessed for HBV coinfection (e.g., HBsAG, anti-HBc), copy of lab work must be received

**AND**

**9** - For regimens that depend on testing [e.g., baseline high fold-change NS5A (nonstructural protein 5A) RASs (resistance-associated substitutions) (includes G1a polymorphisms at amino acid positions 28, 30, 31, or 93), baseline Q80K polymorphism, Y93H mutation], a copy of the lab work must be received

**AND**

**10** - Patient is NOT receiving the requested medication in combination with another HCV direct acting antiviral agent [e.g., sofosbuvir/velpatasvir, Harvoni (ledipasvir/sofosbuvir), Mavyret (glecaprevir/pibrentasvir), Sovaldi (sofosbuvir), Zepatier (elbasvir/grazoprevir)]

**AND**

**11** - The regimen is an approvable regimen, based on patient genotype and characteristics (see Table 2 in Background section)

**AND**

**12** - The provider must submit explanation of medical necessity for brand versus authorized generic

|       |                                                                                         |
|-------|-----------------------------------------------------------------------------------------|
| Notes | Approval length is by regimen based on patient genotype and characteristics in Table 2. |
|-------|-----------------------------------------------------------------------------------------|

Product Name: Brand Harvoni, ledipasvir/sofosbuvir (authorized generic of Harvoni)

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

### **Approval Criteria**

**1** - The requested medication is age-appropriate according to FDA (Food and Drug Administration)-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

**AND**

**2** - Diagnosis of chronic hepatitis C virus (HCV) with labs showing genotype and detectable HCV RNA (ribonucleic acid) levels from within the past 90 days

**AND**

**3** - For treatment-experienced patients, BOTH of the following must be provided:

- Previous treatment history including medication name(s) and length of therapy
- Whether patient is a relapser, null responder, partial responder or non-compliant

**AND**

**4** - Patient has been educated on the importance of compliance with their treatment regimen

**AND**

**5** - All of the following:

**5.1** Patient does not have contraindications to the requested Hepatitis C therapy

**AND**

**5.2** Patient is not on any therapies identified by the prescribing information or American Association for the Study of Liver Diseases/Infectious Diseases Society of America (AASLD/IDSA) guidelines as therapies not recommended for co-administration

**AND**

**5.3** Patient does not have limited life expectancy (< 12 months due to non-liver related comorbidities)

**AND**

**6** - If combined with ribavirin, patient will meet ALL of the following:

**6.1** Patient has no contraindication to ribavirin

**AND**

**6.2** Neither the patient nor the partner of the patient is pregnant

**AND**

**6.3** If the patient or their partner is of child bearing age, the patient has been or will be instructed to practice effective contraception during therapy and for 6 months after stopping ribavirin therapy

**AND**

**7** - For patients with decompensated cirrhosis, the requested drug(s) must be prescribed by or in consultation with a liver transplant specialist

**AND**

**8** - Prior to treatment, patient has been assessed for HBV coinfection (e.g., HBsAG, anti-HBc), copy of lab work must be received

**AND**

**9** - For regimens that depend on testing [e.g., baseline high fold-change NS5A (nonstructural

protein 5A) RASs (resistance-associated substitutions) (includes G1a polymorphisms at amino acid positions 28, 30, 31, or 93), baseline Q80K polymorphism, Y93H mutation], a copy of the lab work must be received

**AND**

**10** - One of the following:

**10.1** Patient is genotype 1 or 4 and has a history of intolerance or contraindication to all of the following (please specify intolerance or contraindication):

- sofosbuvir/velpatasvir (authorized generic of Epclusa)
- Mavyret
- Zepatier

**OR**

**10.2** Patient is genotype 5 or 6 and has a history of intolerance or contraindication to both of the following (please specify intolerance or contraindication):

- sofosbuvir/velpatasvir (authorized generic of Epclusa)
- Mavyret

**OR**

**10.3** Patient is currently on Harvoni (ledipasvir/sofosbuvir) therapy

**AND**

**11** - Patient is NOT receiving the requested medication in combination with another HCV direct acting antiviral agent [e.g., Epclusa (sofosbuvir/velpatasvir), Mavyret (glecaprevir/pibrentasvir), Sovaldi (sofosbuvir), Zepatier (elbasvir/grazoprevir)]

**AND**

**12** - The regimen is an approvable regimen, based on patient genotype and characteristics (see Table 4 in Background section)

|                                                                                                                                  |                                                                                         |
|----------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| <b>AND</b>                                                                                                                       |                                                                                         |
| <b>13</b> - If brand is requested, the provider must submit explanation of medical necessity for brand versus authorized generic |                                                                                         |
| Notes                                                                                                                            | Approval length is by regimen based on patient genotype and characteristics in Table 4. |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                     |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name: Sovaldi                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - The requested medication is age-appropriate according to FDA (Food and Drug Administration)-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Diagnosis of chronic hepatitis C virus (HCV) with labs showing genotype and detectable HCV RNA (ribonucleic acid) levels from within the past 90 days</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - For treatment-experienced patients, BOTH of the following must be provided:</p> <ul style="list-style-type: none"> <li>• Previous treatment history including medication name(s) and length of therapy</li> <li>• Whether patient is a relapser, null responder, partial responder or non-compliant</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>4</b> - Patient has been educated on the importance of compliance with their treatment regimen</p> |                     |

**AND**

**5** - All of the following:

**5.1** Patient does not have contraindications to the requested Hepatitis C therapy

**AND**

**5.2** Patient is not on any therapies identified by the prescribing information or American Association for the Study of Liver Diseases/Infectious Diseases Society of America (AASLD/IDSA) guidelines as therapies not recommended for co-administration

**AND**

**5.3** Patient does not have limited life expectancy (< 12 months due to non-liver related comorbidities)

**AND**

**6** - If combined with ribavirin, patient will meet ALL of the following:

**6.1** Patient has no contraindication to ribavirin

**AND**

**6.2** Neither the patient nor the partner of the patient is pregnant

**AND**

**6.3** If the patient or their partner is of child bearing age, the patient has been or will be instructed to practice effective contraception during therapy and for 6 months after stopping ribavirin therapy

**AND**



**7** - For patients with decompensated cirrhosis, the requested drug(s) must be prescribed by or in consultation with a liver transplant specialist

**AND**

**8** - Prior to treatment, patient has been assessed for HBV coinfection (e.g., HBsAG, anti-HBc), copy of lab work must be received

**AND**

**9** - For regimens that depend on testing [e.g., baseline high fold-change NS5A (nonstructural protein 5A) RASs (resistance-associated substitutions) (includes G1a polymorphisms at amino acid positions 28, 30, 31, or 93), baseline Q80K polymorphism, Y93H mutation], a copy of the lab work must be received

**AND**

**10** - One of the following:

**10.1** Patient is genotype 1 or 4 and has a history of intolerance or contraindication to all of the following (please specify intolerance or contraindication):

- sofosbuvir/velpatasvir (authorized generic of Epclusa)
- Mavyret
- Zepatier

**OR**

**10.2** Patient is genotype 2 or 3 and has a history of intolerance or contraindication to both of the following (please specify intolerance or contraindication):

- sofosbuvir/velpatasvir (authorized generic of Epclusa)
- Mavyret

**OR**

**10.3** Patient is currently on Sovaldi therapy

**AND**

**11** - Patient is NOT receiving the requested medication in combination with another HCV direct acting antiviral agent [e.g., Epclusa (sofosbuvir/velpatasvir), Harvoni (ledipasvir/sofosbuvir), Mavyret (glecaprevir/pibrentasvir), Zepatier (elbasvir/grazoprevir)]

**AND**

**12** - The regimen is an approvable regimen, based on patient genotype and characteristics (see Table 5 in Background section)

|       |                                                                                         |
|-------|-----------------------------------------------------------------------------------------|
| Notes | Approval length is by regimen based on patient genotype and characteristics in Table 5. |
|-------|-----------------------------------------------------------------------------------------|

Product Name: Vosevi

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

### Approval Criteria

**1** - The requested medication is age-appropriate according to FDA (Food and Drug Administration)-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

**AND**

**2** - Diagnosis of chronic hepatitis C virus (HCV) with labs showing genotype and detectable HCV RNA (ribonucleic acid) levels from within the past 90 days

**AND**

**3** - For treatment-experienced patients, BOTH of the following must be provided:

- Previous treatment history including medication name(s) and length of therapy
- Whether patient is a relapser, null responder, partial responder or non-compliant

**AND**

**4** - Patient has been educated on the importance of compliance with their treatment regimen

**AND**

**5** - All of the following:

**5.1** Patient does not have contraindications to the requested Hepatitis C therapy

**AND**

**5.2** Patient is not on any therapies identified by the prescribing information or American Association for the Study of Liver Diseases/Infectious Diseases Society of America (AASLD/IDSA) guidelines as therapies not recommended for co-administration

**AND**

**5.3** Patient does not have limited life expectancy (< 12 months due to non-liver related comorbidities)

**AND**

**6** - If combined with ribavirin, patient will meet ALL of the following:

**6.1** Patient has no contraindication to ribavirin

**AND**

**6.2** Neither the patient nor the partner of the patient is pregnant

**AND**

**6.3** If the patient or their partner is of child bearing age, the patient has been or will be

instructed to practice effective contraception during therapy and for 6 months after stopping ribavirin therapy

**AND**

**7** - For patients with decompensated cirrhosis, the requested drug(s) must be prescribed by or in consultation with a liver transplant specialist

**AND**

**8** - Prior to treatment, patient has been assessed for HBV coinfection (e.g., HBsAG, anti-HBc), copy of lab work must be received

**AND**

**9** - For regimens that depend on testing [e.g., baseline high fold-change NS5A (nonstructural protein 5A) RASs (resistance-associated substitutions) (includes G1a polymorphisms at amino acid positions 28, 30, 31, or 93), baseline Q80K polymorphism, Y93H mutation], a copy of the lab work must be received

**AND**

**10** - One of the following:

**10.1** Both of the following:

**10.1.1** Patient is genotype 1, 2, 3, 4, 5, or 6 and had virologic failure after completing previous treatment of at least 4 weeks' duration with an HCV regimen containing an NS5A inhibitor as confirmed by claims history or submission of medical records

**AND**

**10.1.2** If patient is genotype 1 and has not been previously treated with an NS3/4A inhibitor, history of intolerance or contraindication to Mavyret (please specify intolerance or contraindication)

**OR**

**10.2** All of the following:

**10.2.1** Patient is genotype 1a or 3 and had virologic failure after completing previous treatment of at least 4 weeks' duration with an HCV regimen containing sofosbuvir without an NS5A inhibitor as confirmed by claims history or submission of medical records

**AND**

**10.2.2** If patient is genotype 1a and has been treated with or without an NS3/4A inhibitor, history of intolerance or contraindication to Mavyret (please specify intolerance or contraindication)

**AND**

**10.2.3** If patient is genotype 3 and has not been treated with an NS3/4A inhibitor, history of intolerance or contraindication to Mavyret (please specify intolerance or contraindication)

**OR**

**10.3** Patient is currently on Vosevi therapy

**AND**

**11** - The patient is without cirrhosis or has compensated cirrhosis (Child-Pugh A)

**AND**

**12** - Patient is NOT receiving the requested medication in combination with another HCV direct acting antiviral agent [e.g., Epclusa (sofosbuvir/velpatasvir), Harvoni (ledipasvir/sofosbuvir), Mavyret (glecaprevir/pibrentasvir), Sovaldi (sofosbuvir), Zepatier (elbasvir/grazoprevir)]

**AND**

**13** - The regimen is an approvable regimen, based on patient genotype and characteristics (see Table 6 in Background section)

|       |                                                                                         |
|-------|-----------------------------------------------------------------------------------------|
| Notes | Approval length is by regimen based on patient genotype and characteristics in Table 6. |
|-------|-----------------------------------------------------------------------------------------|

## 2 . Background

### Benefit/Coverage/Program Information

**Table 1. Mavyret**

#### Treatment Experienced Patients

| HCV Genotype     | Patients previously treated with a regimen containing:                                                                                                                                        | Treatment Duration |                                      |
|------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|--------------------------------------|
|                  |                                                                                                                                                                                               | No cirrhosis       | Compensated cirrhosis (Child-Pugh A) |
| 1                | An NS5A inhibitor <sup>1</sup><br>[e.g., Daklinza (daclatasvir), Epclusa (sofosbuvir/velpatasvir), Harvoni (ledipasvir/sofosbuvir)] without prior treatment with an NS3/4A protease inhibitor | 16 weeks           | 16 weeks                             |
|                  | An NS3/4A PI <sup>2</sup> [e.g., Incivek (telaprevir), Victrelis (boceprevir)] without prior treatment with an NS5A inhibitor                                                                 | 12 weeks           | 12 weeks                             |
| 1, 2, 4, 5, or 6 | PRS <sup>3</sup>                                                                                                                                                                              | 8 weeks            | 12 weeks                             |
| 3                | PRS <sup>3</sup>                                                                                                                                                                              | 16 weeks           | 16 weeks                             |

#### Kidney Transplant Recipients

| HCV Genotype | Treatment Duration |                                      |
|--------------|--------------------|--------------------------------------|
|              | No cirrhosis       | Compensated cirrhosis (Child-Pugh A) |

|                     |          |          |
|---------------------|----------|----------|
| 1, 2, 3, 4, 5, or 6 | 12 weeks | 12 weeks |
|---------------------|----------|----------|

1. In clinical trials, subjects were treated with prior regimens containing ledipasvir and sofosbuvir or daclatasvir with pegylated interferon and ribavirin.
2. In clinical trials, subjects were treated with prior regimens containing simeprevir and sofosbuvir, or simeprevir, boceprevir, or telaprevir with pegylated interferon and ribavirin.
3. PRS = prior treatment experience with regimens containing interferon, pegylated interferon, ribavirin, and/or sofosbuvir, but no prior treatment experience with an HCV NS3/4A PI [e.g., Incivek (telaprevir), Victrelis (boceprevir), Viekira (dasabuvir/ombitasvir/paritaprevir/ritonavir), Zepatier (elbasvir/grazoprevir)] or NS5A inhibitor [e.g., Daklinza (daclatasvir), Epclusa (sofosbuvir/velpatasvir), Harvoni (ledipasvir/sofosbuvir), Viekira (dasabuvir/ombitasvir/paritaprevir/ritonavir), Zepatier (elbasvir/grazoprevir)].

**Table 2. Epclusa or sofosbuvir/velpatasvir (authorized generic of Epclusa)**

| Patient Population                                                                    | Recommended Treatment Regimen                             |
|---------------------------------------------------------------------------------------|-----------------------------------------------------------|
| Patients <sup>1</sup> without cirrhosis and with compensated cirrhosis (Child-Pugh A) | EPCLUSA (sofosbuvir/velpatasvir) for 12 weeks             |
| Patients <sup>1</sup> with decompensated cirrhosis (Child-Pugh B and C)               | EPCLUSA (sofosbuvir/velpatasvir) + ribavirin for 12 weeks |

1 = In clinical trials, regimens contained peginterferon alfa/ribavirin with or without an HCV NS3/4A protease inhibitor (boceprevir, simeprevir, or telaprevir)

**Table 3: Zepatier**
**Dosage Regimens and Durations for ZEPATIER in Patients with Genotype 1 or 4 HCV with or without Cirrhosis**

| Patient Population                                                                           | Treatment            | Duration |
|----------------------------------------------------------------------------------------------|----------------------|----------|
| Genotype 1a: PegIFN/RBV experienced* <u>without</u> baseline NS5A polymorphisms <sup>+</sup> | ZEPATIER             | 12 weeks |
| Genotype 1a: PegIFN/RBV                                                                      | ZEPATIER + ribavirin | 16 weeks |

|                                                                   |                      |          |
|-------------------------------------------------------------------|----------------------|----------|
| experienced* <u>with</u> baseline NS5A polymorphisms <sup>+</sup> |                      |          |
| Genotype 1b: PegIFN/RBV experienced*                              | ZEPATIER             | 12 weeks |
| Genotype 1a or 1b: PegIFN/RBV/PI experienced <sup>++</sup>        | ZEPATIER + ribavirin | 12 weeks |
| Genotype 4: PegIFN/RBV experienced*                               | ZEPATIER + ribavirin | 16 weeks |

\*Peginterferon alfa + ribavirin

+Polymorphisms at amino acid positions 28, 30, 31, or 93

++Peginterferon alfa + ribavirin + HCV NS3/4 A protease inhibitor

**Table 4. Harvoni or ledipasvir/sofosbuvir (authorized generic of Harvoni)**

**Recommended treatment regimen and duration:**

| Genotype        | Patient Population                                                                                 | Regimen and Duration          |
|-----------------|----------------------------------------------------------------------------------------------------|-------------------------------|
| Genotype 1      | Treatment-naïve without cirrhosis or with compensated cirrhosis (Child-Pugh A)                     | HARVONI 12 weeks*             |
|                 | Treatment-experienced** without cirrhosis                                                          | HARVONI 12 weeks              |
|                 | Treatment-experienced** with compensated cirrhosis (Child-Pugh A)                                  | HARVONI 24 weeks <sup>+</sup> |
|                 | Treatment-naïve and treatment-experienced** with decompensated cirrhosis (Child-Pugh B or C)       | HARVONI + ribavirin 12 weeks  |
| Genotype 1 or 4 | Treatment-naïve and treatment-experienced** liver transplant recipients without cirrhosis, or with | HARVONI + ribavirin 12 weeks  |



|                     |                                                                                                            |                  |
|---------------------|------------------------------------------------------------------------------------------------------------|------------------|
|                     | compensated cirrhosis (Child-Pugh A)                                                                       |                  |
| Genotype 4, 5, or 6 | Treatment-naïve and treatment-experienced** without cirrhosis or with compensated cirrhosis (Child-Pugh A) | HARVONI 12 weeks |

\*HARVONI for 8 weeks can be considered in treatment-naïve genotype 1 patients without cirrhosis who have pre-treatment HCV RNA less than 6 million IU/mL

(Harvoni once daily for 8 weeks is recommended for treatment-naïve patients without cirrhosis who are non-black, HIV-uninfected, and whose HCV RNA level is <6 million IU/mL)

\*\*Treatment-experienced adult and pediatric patients have failed a peginterferon alfa +/- ribavirin based regimen with or without an HCV protease inhibitor

+HARVONI + ribavirin for 12 weeks can be considered in treatment-experienced genotype 1 patients with cirrhosis who are eligible for ribavirin

**Table 5. Sovaldi**

**Recommended Adult Treatment Regimen and Duration**

|                 | <b>Adult Patient Population</b>                                                                           | <b>Regimen and Duration</b>                          |
|-----------------|-----------------------------------------------------------------------------------------------------------|------------------------------------------------------|
| Genotype 1 or 4 | Treatment naïve without cirrhosis or with compensated cirrhosis (Child-Pugh A)                            | SOVALDI + peginterferon alfa + ribavirin<br>12 weeks |
| Genotype 2      | Treatment naïve and treatment experienced* without cirrhosis or with compensated cirrhosis (Child-Pugh A) | SOVALDI + ribavirin<br>12 weeks                      |
| Genotype 3      | Treatment naïve and treatment experienced* without cirrhosis or with compensated cirrhosis (Child-Pugh A) | SOVALDI + ribavirin<br>24 weeks                      |

SOVALDI in combination with ribavirin for 24 weeks can be considered for adult patients with genotype 1 infection who are interferon ineligible.

SOVALDI should be used in combination with ribavirin for treatment of HCV in adult patients with hepatocellular carcinoma awaiting liver transplantation for up to 48 weeks or until liver transplantation, whichever occurs first.

\*Treatment-experienced patients have failed an interferon based regimen with or without ribavirin

**Recommended Treatment Regimen and Duration for Pediatric Patients 3 Years of Age and Older**

|            | <b>Pediatric Patient Population 3 Years of Age and Older</b>                                              | <b>Regimen and Duration</b>     |
|------------|-----------------------------------------------------------------------------------------------------------|---------------------------------|
| Genotype 2 | Treatment naïve and treatment experienced* without cirrhosis or with compensated cirrhosis (Child-Pugh A) | SOVALDI + ribavirin<br>12 weeks |
| Genotype 3 | Treatment naïve and treatment experienced* without cirrhosis or with compensated cirrhosis (Child-Pugh A) | SOVALDI + ribavirin<br>24 weeks |

\*Treatment experienced patients have failed an interferon based regimen with or without ribavirin

**Table 6. Vosevi**

| <b>Genotype</b>     | <b>Patients previously treated with an HCV regimen containing:</b> | <b>VOSEVI Duration</b> |
|---------------------|--------------------------------------------------------------------|------------------------|
| 1, 2, 3, 4, 5, or 6 | An NS5A inhibitor <sup>1</sup>                                     | 12 weeks               |
| 1a or 3             | Sofosbuvir without an NS5A inhibitor <sup>2</sup>                  | 12 weeks               |

1. In clinical trials, prior NS5A inhibitor experience included daclatasvir, elbasvir, ledipasvir, ombitasvir, or velpatasvir.

2. In clinical trials, prior treatment experience included sofosbuvir with or without any of the following: peginterferon alfa/ribavirin, ribavirin, HCV NS3/4A protease inhibitor (boceprevir, simeprevir or telaprevir).

### 3 . Revision History

| Date      | Notes                                                                                                                     |
|-----------|---------------------------------------------------------------------------------------------------------------------------|
| 6/13/2024 | Removed Viekira. Updated state criteria and treatment naïve criteria for point of sale quick check on preferred products. |

Hetlioz



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|-----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-236201                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Guideline Name</b> | Hetlioz                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 6/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                                                              |                       |
|--------------------------------------------------------------|-----------------------|
| Product Name: Brand Hetlioz, generic tasimelteon, Hetlioz LQ |                       |
| Approval Length                                              | 12 month(s)           |
| Therapy Stage                                                | Initial Authorization |
| Guideline Type                                               | Prior Authorization   |
| <b>Approval Criteria</b>                                     |                       |

**1 - ONE of the following:**

**1.1 BOTH of the following:**

- Diagnosis of non-24-hour sleep wake disorder (also known as free-running disorder, free-running or non-entrained type circadian rhythm sleep disorder, or hypernycthemeral syndrome)
- Patient is totally blind (has no light perception)

**OR**

**1.2** Diagnosis of nighttime sleep disturbances in Smith-Magenis-Syndrome (SMS)

**AND**

**2 - ONE of the following:**

**2.1** History of contraindication or intolerance to melatonin therapy (please specify contraindication or intolerance)

**OR**

**2.2 BOTH of the following:**

- Failure of at least 6 months of continuous therapy (i.e., uninterrupted daily treatment) with melatonin, as confirmed by claims history or submission of medical records
- Continuous trial of melatonin was done under the guidance of a specialist in sleep disorders

**AND**

**3 - Prescribed by or in consultation with a specialist in sleep disorders**

|                                                              |                     |
|--------------------------------------------------------------|---------------------|
| Product Name: Brand Hetlioz, generic tasimelteon, Hetlioz LQ |                     |
| Approval Length                                              | 12 month(s)         |
| Therapy Stage                                                | Reauthorization     |
| Guideline Type                                               | Prior Authorization |

**Approval Criteria**

1 - Documentation of positive clinical response to therapy

**2 . Revision History**

| Date     | Notes                                                             |
|----------|-------------------------------------------------------------------|
| 4/7/2025 | Updated formularies. Increased initial auth duration to 12 months |

Hycamtin



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-138234                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Guideline Name</b> | Hycamtin                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 2/1/2024 |
|-----------------|----------|

## 1 . Criteria

|                                                 |                               |
|-------------------------------------------------|-------------------------------|
| Product Name: Brand Hycamtin, generic topotecan |                               |
| Diagnosis                                       | Small Cell Lung Cancer (SCLC) |
| Approval Length                                 | 12 month(s)                   |
| Therapy Stage                                   | Initial Authorization         |
| Guideline Type                                  | Prior Authorization           |

**Approval Criteria**

**1** - Diagnosis of small cell lung cancer (SCLC)

**AND**

**2** - Patient has experienced a relapse of disease after initial first-line chemotherapy (e.g., cisplatin with etoposide)

Product Name: Brand Hycamtin, generic topotecan

|           |                       |
|-----------|-----------------------|
| Diagnosis | Merkel Cell Carcinoma |
|-----------|-----------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

**1** - Diagnosis of Merkel cell carcinoma

**AND**

**2** - Disease is M1 disseminated

**AND**

**3** - Patient has a contraindication to or disease has progressed on anti-PD-L1 or anti-PD-1 therapy

Product Name: Brand Hycamtin, generic topotecan

|           |                                                      |
|-----------|------------------------------------------------------|
| Diagnosis | Small Cell Lung Cancer (SCLC), Merkel Cell Carcinoma |
|-----------|------------------------------------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|



|                                                                                                                                 |                     |
|---------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Therapy Stage                                                                                                                   | Reauthorization     |
| Guideline Type                                                                                                                  | Prior Authorization |
| <b>Approval Criteria</b><br><br>1 - Patient does not show evidence of progressive disease while on Hycamtin (topotecan) therapy |                     |

|                                                                                                                                         |                           |
|-----------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Brand Hycamtin, generic topotecan                                                                                          |                           |
| Diagnosis                                                                                                                               | NCCN Recommended Regimens |
| Approval Length                                                                                                                         | 12 month(s)               |
| Therapy Stage                                                                                                                           | Initial Authorization     |
| Guideline Type                                                                                                                          | Prior Authorization       |
| <b>Approval Criteria</b><br><br>1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium |                           |

|                                                                                                                 |                           |
|-----------------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Brand Hycamtin, generic topotecan                                                                  |                           |
| Diagnosis                                                                                                       | NCCN Recommended Regimens |
| Approval Length                                                                                                 | 12 month(s)               |
| Therapy Stage                                                                                                   | Reauthorization           |
| Guideline Type                                                                                                  | Prior Authorization       |
| <b>Approval Criteria</b><br><br>1 - Documentation of positive clinical response to Hycamtin (topotecan) therapy |                           |

## 2 . Revision History

| Date       | Notes                                                                         |
|------------|-------------------------------------------------------------------------------|
| 12/27/2023 | Updated Merkel cell carcinoma criteria based on current NCCN recommendations. |

Hyftor



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-135121                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Guideline Name</b> | Hyftor                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 1/1/2024 |
|-----------------|----------|

## 1 . Criteria

|                     |                       |
|---------------------|-----------------------|
| Product Name:Hyftor |                       |
| Approval Length     | 6 month(s)            |
| Therapy Stage       | Initial Authorization |
| Guideline Type      | Prior Authorization   |
|                     |                       |

## **Approval Criteria**

**1** - Diagnosis of tuberous sclerosis

**AND**

**2** - One of the following:

**2.1** One or more of the following major features:

- Hypomelanotic macules (At least 3; at least 5 mm diameter)
- Angiofibroma (At least 3) or fibrous cephalic plaque
- Ungual fibromas (At least 2)
- Shagreen patch
- Multiple retinal hamartomas
- Multiple cortical tubers and/or radial migration lines
- Subependymal nodule (At least 2)
- Subependymal giant cell astrocytoma
- Cardiac rhabdomyoma
- Lymphangiomyomatosis (LAM)
- Angiomyolipomas (At least 2)

**OR**

**2.2** Two or more of the following minor features:

- “Confetti” skin lesions
- Dental enamel pits (At least 3)
- Intraoral fibromas (At least 2)
- Retinal achromic patch
- Multiple renal cysts
- Nonrenal hamartomas
- Sclerotic bone lesions

**OR**

**2.3** Confirmed presence of a mutation in the TSC1 or TSC2 gene

**AND**

**3** - Patient has facial angiofibroma associated with tuberous sclerosis

**AND**

**4** - Patient is not receiving Hyftor in combination with a systemic mTOR (mechanistic target of rapamycin) inhibitor [e.g., Rapamune (sirolimus), Afinitor (everolimus)]

**AND**

**5** - Hyftor is being prescribed by, or in consultation, with a dermatologist, neurologist, or oncologist

Product Name:Hyftor

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                 |
|---------------|-----------------|
| Therapy Stage | Reauthorization |
|---------------|-----------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

### Approval Criteria

**1** - Documentation of positive clinical response to therapy (e.g., improvement in skin lesions)

**AND**

**2** - Patient is not receiving Hyftor in combination with a systemic mTOR inhibitor [e.g., Rapamune (sirolimus), Afinitor (everolimus)]

**AND**

**3** - Hyftor is being prescribed by, or in consultation, with a dermatologist, neurologist, or oncologist

## 2 . Revision History

UnitedHealthcare Community Plan of New Jersey – Clinical Pharmacy Guidelines

| Date       | Notes                   |
|------------|-------------------------|
| 10/17/2023 | Removed RMHCO formulary |

Hypmavzi



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-402257                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Guideline Name</b> | Hypmavzi                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 11/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                       |                                 |
|-----------------------|---------------------------------|
| Product Name:Hypmavzi |                                 |
| Diagnosis             | Hemophilia A Without Inhibitors |
| Approval Length       | 12 month(s)                     |
| Therapy Stage         | Initial Authorization           |
| Guideline Type        | Prior Authorization             |

**Approval Criteria**

1 - Diagnosis of hemophilia A

**AND**

2 - Patient has not developed high-titer factor VIII inhibitors (i.e., patient has NOT developed factor VIII inhibitors greater than or equal to 5 Bethesda units [BU])

**AND**

3 - Patient is 12 years of age or older

**AND**

4 - Himpavzi is prescribed for the prevention of bleeding episodes (i.e., routine prophylaxis)

|                                                                                                            |                                 |
|------------------------------------------------------------------------------------------------------------|---------------------------------|
| Product Name:Himpavzi                                                                                      |                                 |
| Diagnosis                                                                                                  | Hemophilia A Without Inhibitors |
| Approval Length                                                                                            | 12 month(s)                     |
| Therapy Stage                                                                                              | Reauthorization                 |
| Guideline Type                                                                                             | Prior Authorization             |
| <p><b>Approval Criteria</b></p> <p>1 - Documentation of positive clinical response to Himpavzi therapy</p> |                                 |

|                       |                                 |
|-----------------------|---------------------------------|
| Product Name:Himpavzi |                                 |
| Diagnosis             | Hemophilia B Without Inhibitors |
| Approval Length       | 12 month(s)                     |



|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                       |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of hemophilia B</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Patient has not developed high-titer factor IX inhibitors (i.e., patient has NOT developed factor IX inhibitors greater than or equal to 5 Bethesda units [BU])</p> <p style="text-align: center;"><b>AND</b></p> <p>3 - Patient is 12 years of age or older</p> <p style="text-align: center;"><b>AND</b></p> <p>4 - Hymravzi is prescribed for the prevention of bleeding episodes (i.e., routine prophylaxis)</p> |                       |

|                                                                                                            |                                 |
|------------------------------------------------------------------------------------------------------------|---------------------------------|
| Product Name:Hymravzi                                                                                      |                                 |
| Diagnosis                                                                                                  | Hemophilia B Without Inhibitors |
| Approval Length                                                                                            | 12 month(s)                     |
| Therapy Stage                                                                                              | Reauthorization                 |
| Guideline Type                                                                                             | Prior Authorization             |
| <p><b>Approval Criteria</b></p> <p>1 - Documentation of positive clinical response to Hymravzi therapy</p> |                                 |

## 2 . Revision History

| Date      | Notes                                                                                        |
|-----------|----------------------------------------------------------------------------------------------|
| 9/30/2025 | Criteria updated. Clarified high titer inhibitor criteria. Removed note from reauth section. |

Ibrance



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-402265                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Guideline Name</b> | Ibrance                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 11/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                      |                       |
|----------------------|-----------------------|
| Product Name:Ibrance |                       |
| Diagnosis            | Breast Cancer         |
| Approval Length      | 12 month(s)           |
| Therapy Stage        | Initial Authorization |

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Prior Authorization |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of advanced, recurrent, or metastatic breast cancer</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Disease is hormone-receptor (HR)-positive</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Disease is human epidermal growth factor receptor 2 (HER2)-negative</p> <p style="text-align: center;"><b>AND</b></p> <p><b>4</b> - ONE of the following:</p> <ul style="list-style-type: none"> <li>• Used in combination with an aromatase inhibitor (e.g., anastrozole, letrozole, exemestane)</li> <li>• Used in combination with Faslodex (fulvestrant)</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>5</b> - For PIK3CA activating mutation-negative disease, BOTH of the following:</p> <p><b>5.1</b> Disease is ONE of the following:</p> <p><b>5.1.1</b> Recurrent unresectable (local or regional)</p> <p style="text-align: center;"><b>OR</b></p> <p><b>5.1.2</b> Stage IV (M1)</p> |                     |

**AND**

**5.2** ONE of the following:

**5.2.1** ONE of the following:

- Failure to Verzenio (abemaciclib) confirmed by claims history or submission of medical records
- History of contraindication or intolerance to Verzenio (abemaciclib) (please specify intolerance or contraindication)

**OR**

**5.2.2** Patient is currently on Ibrance therapy

| Product Name:Ibrance                                                                                                                            |                                                            |
|-------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------|
| Diagnosis                                                                                                                                       | Well-Differentiated/Dedifferentiated Liposarcoma (WD-DDLS) |
| Approval Length                                                                                                                                 | 12 month(s)                                                |
| Therapy Stage                                                                                                                                   | Initial Authorization                                      |
| Guideline Type                                                                                                                                  | Prior Authorization                                        |
| <b>Approval Criteria</b><br><br><b>1</b> - Diagnosis of unresectable retroperitoneal WD-DDLS (well-differentiated/dedifferentiated liposarcoma) |                                                            |

| Product Name:Ibrance |                                                                           |
|----------------------|---------------------------------------------------------------------------|
| Diagnosis            | Breast Cancer, Well-Differentiated/Dedifferentiated Liposarcoma (WD-DDLS) |
| Approval Length      | 12 month(s)                                                               |
| Therapy Stage        | Reauthorization                                                           |
| Guideline Type       | Prior Authorization                                                       |

**Approval Criteria**

1 - Patient does not show evidence of progressive disease while on Ibrance therapy

**Product Name:Ibrance**

|           |                           |
|-----------|---------------------------|
| Diagnosis | NCCN Recommended Regimens |
|-----------|---------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

**Product Name:Ibrance**

|           |                           |
|-----------|---------------------------|
| Diagnosis | NCCN Recommended Regimens |
|-----------|---------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                 |
|---------------|-----------------|
| Therapy Stage | Reauthorization |
|---------------|-----------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

1 - Documentation of positive clinical response to Ibrance therapy

## 2 . Revision History

| Date | Notes |
|------|-------|
|------|-------|

|           |                                             |
|-----------|---------------------------------------------|
| 9/30/2025 | Updated breast cancer criteria. Removed IN. |
|-----------|---------------------------------------------|



Ibuprofen



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-406200                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Guideline Name</b> | Ibuprofen                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Washington (ACUWA, ACUWAAHE, ACUWAC)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 11/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                        |                                    |
|------------------------|------------------------------------|
| Product Name:Ibuprofen |                                    |
| Diagnosis              | Non-Small Cell Lung Cancer (NSCLC) |
| Approval Length        | 12 month(s)                        |



|                                                                                                                                                                                                                                                                                                                                                         |                       |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                                                                                                                                                                                                                                                                                           | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                          | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of non-small cell lung cancer (NSCLC)</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Disease is ONE of the following:</p> <ul style="list-style-type: none"> <li>• Metastatic</li> <li>• Advanced</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p>3 - Tumor is ROS1-positive</p> |                       |

|                                                                                                                             |                                    |
|-----------------------------------------------------------------------------------------------------------------------------|------------------------------------|
| Product Name:Ibuprofen                                                                                                      |                                    |
| Diagnosis                                                                                                                   | Non-Small Cell Lung Cancer (NSCLC) |
| Approval Length                                                                                                             | 12 month(s)                        |
| Therapy Stage                                                                                                               | Reauthorization                    |
| Guideline Type                                                                                                              | Prior Authorization                |
| <p><b>Approval Criteria</b></p> <p>1 - Patient does not show evidence of progressive disease while on Ibuprofen therapy</p> |                                    |

|                        |                           |
|------------------------|---------------------------|
| Product Name:Ibuprofen |                           |
| Diagnosis              | NCCN Recommended Regimens |
| Approval Length        | 12 month(s)               |
| Therapy Stage          | Initial Authorization     |

|                                                                                                                                                |                     |
|------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Guideline Type                                                                                                                                 | Prior Authorization |
| <b>Approval Criteria</b><br><br><b>1</b> - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium |                     |

|                                                                                                           |                           |
|-----------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Ibtrozi                                                                                      |                           |
| Diagnosis                                                                                                 | NCCN Recommended Regimens |
| Approval Length                                                                                           | 12 month(s)               |
| Therapy Stage                                                                                             | Reauthorization           |
| Guideline Type                                                                                            | Prior Authorization       |
| <b>Approval Criteria</b><br><br><b>1</b> - Documentation of positive clinical response to Ibtrozi therapy |                           |

## 2 . Revision History

| Date      | Notes        |
|-----------|--------------|
| 10/6/2025 | New Program. |

Iclusig



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-138211                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Guideline Name</b> | Iclusig                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 2/1/2024 |
|-----------------|----------|

## 1 . Criteria

|                      |                                              |
|----------------------|----------------------------------------------|
| Product Name:Iclusig |                                              |
| Diagnosis            | Chronic Myelogenous / Myeloid Leukemia (CML) |
| Approval Length      | 12 month(s)                                  |
| Therapy Stage        | Initial Authorization                        |
| Guideline Type       | Prior Authorization                          |

## Approval Criteria

1 - Diagnosis of chronic myelogenous/ myeloid leukemia (CML)

**AND**

2 - One of the following:

2.1 BOTH of the following:

- Disease is in the chronic phase
- Patient has resistance or intolerance to two or more tyrosine kinase inhibitor (TKI) therapies [e.g., imatinib mesylate, Sprycel (dasatinib), or Tasigna (nilotinib)]

**OR**

2.2 Confirmed documentation of T315I mutation

**OR**

2.3 BOTH of the following:

- Disease is in the accelerated or blast phase
- No other kinase inhibitors are indicated

| Product Name:Iclusig |                                                                        |
|----------------------|------------------------------------------------------------------------|
| Diagnosis            | Philadelphia Chromosome-Positive Acute Lymphoblastic Leukemia (Ph+ALL) |
| Approval Length      | 12 month(s)                                                            |
| Therapy Stage        | Initial Authorization                                                  |
| Guideline Type       | Prior Authorization                                                    |
|                      |                                                                        |

**Approval Criteria**

1 - Diagnosis of Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ALL)

Product Name:Iclusig

|           |                            |
|-----------|----------------------------|
| Diagnosis | Myeloid/Lymphoid Neoplasms |
|-----------|----------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

1 - Diagnosis of lymphoid, myeloid, or mixed lineage neoplasms with eosinophilia

**AND**

2 - One of the following:

2.1 Patient has a FGFR1 (fibroblast growth factor receptor 1) rearrangement

**OR**

2.2 Patient has an ABL1 (gene) rearrangement

Product Name:Iclusig

|           |                                        |
|-----------|----------------------------------------|
| Diagnosis | Gastrointestinal Stromal Tumors (GIST) |
|-----------|----------------------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

**1 - Diagnosis of gastrointestinal stromal tumor (GIST)**

**AND**

**2 - Disease is ONE of the following:**

- Gross residual disease (R2 resection)
- Unresectable primary disease
- Tumor rupture
- Recurrent/metastatic disease after progression on approved therapies (e.g. imatinib, sunitinib, regorafenib, and standard dose ripretinib)

**Product Name: Iclusig**

|                 |                                                                                                                                                                                          |
|-----------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Diagnosis       | Chronic Myelogenous / Myeloid Leukemia (CML), Philadelphia Chromosome-Positive Acute Lymphoblastic Leukemia (Ph+ALL), Myeloid/Lymphoid Neoplasms, Gastrointestinal Stromal Tumors (GIST) |
| Approval Length | 12 month(s)                                                                                                                                                                              |
| Therapy Stage   | Reauthorization                                                                                                                                                                          |
| Guideline Type  | Prior Authorization                                                                                                                                                                      |

**Approval Criteria**

**1 - Patient does not show evidence of progressive disease while on Iclusig therapy**

**Product Name: Iclusig**

|                 |                          |
|-----------------|--------------------------|
| Diagnosis       | NCCN Recommended Regimen |
| Approval Length | 12 month(s)              |
| Therapy Stage   | Initial Authorization    |
| Guideline Type  | Prior Authorization      |

**Approval Criteria**

**1** - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

|                                                                                                           |                          |
|-----------------------------------------------------------------------------------------------------------|--------------------------|
| Product Name:Iclusig                                                                                      |                          |
| Diagnosis                                                                                                 | NCCN Recommended Regimen |
| Approval Length                                                                                           | 12 month(s)              |
| Therapy Stage                                                                                             | Reauthorization          |
| Guideline Type                                                                                            | Prior Authorization      |
| <b>Approval Criteria</b><br><br><b>1</b> - Documentation of positive clinical response to Iclusig therapy |                          |

## 2 . Revision History

| Date     | Notes                                                                                                          |
|----------|----------------------------------------------------------------------------------------------------------------|
| 1/8/2024 | Updated Ph+ ALL criteria based on NCCN recommendations. Added criteria for GIST based on NCCN recommendations. |

ICS.LABA Combination Products



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-444196                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Guideline Name</b> | ICS.LABA Combination Products                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 12/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                                                            |                     |
|------------------------------------------------------------|---------------------|
| Product Name:Generic Breyna, generic budesonide/formoterol |                     |
| Approval Length                                            | 12 month(s)         |
| Guideline Type                                             | Prior Authorization |
| Approval Criteria                                          |                     |



**1 - ONE of the following:**

**1.1 BOTH of the following:**

**1.1.1** Diagnosis of chronic obstructive pulmonary disease (COPD)

**AND**

**1.1.2 ONE of the following:**

**1.1.2.1** Failure of ONE of the following confirmed by claims history or submitted medical records

- fluticasone propionate/salmeterol diskus (generic Advair Diskus)
- Wixela Inhub (generic Advair Diskus)

**OR**

**1.1.2.2** History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- fluticasone propionate/salmeterol diskus (generic Advair Diskus)
- Wixela Inhub (generic Advair Diskus)

**OR**

**1.2 BOTH of the following:**

**1.2.1** Diagnosis of asthma

**AND**

**1.2.2 ONE of the following:**

**1.2.2.1** Patient is less than 12 years of age

**OR**

**1.2.2.2 ONE of the following:**

**1.2.2.2.1** Failure of ONE of the following confirmed by claims history or submitted medical records:

- fluticasone/salmeterol (authorized generic of AirDuo Respiclick)
- fluticasone propionate/salmeterol diskus (generic Advair Diskus)
- Wixela Inhub (generic Advair Diskus)

**OR**

**1.2.2.2.2** History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication):

- fluticasone/salmeterol (authorized generic of AirDuo Respiclick)
- fluticasone propionate/salmeterol diskus (generic Advair Diskus)
- Wixela Inhub (generic Advair Diskus)

|                                                                                                                                                                                                                                                                                                            |                     |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name: Fluticasone/vilanterol (authorized generic of Breo Ellipta)                                                                                                                                                                                                                                  |                     |
| Approval Length                                                                                                                                                                                                                                                                                            | 12 month(s)         |
| Guideline Type                                                                                                                                                                                                                                                                                             | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1 - BOTH of the following:</b></p> <p><b>1.1</b> Diagnosis of asthma</p> <p style="text-align: center;"><b>AND</b></p> <p><b>1.2</b> BOTH of the following:</p> <p><b>1.2.1</b> ONE of the following:</p> <p><b>1.2.1.1</b> Patient is less than 12 years of age</p> |                     |

**OR**

**1.2.1.2** Failure of ONE of the following confirmed by claims history or submitted medical records:

- fluticasone/salmeterol (authorized generic of AirDuo Resplick)
- fluticasone propionate/salmeterol diskus (generic Advair Diskus)
- Wixela Inhub (generic Advair Diskus)

**OR**

**1.2.1.3** History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication):

- fluticasone/salmeterol (authorized generic of AirDuo Resplick)
- fluticasone propionate/salmeterol diskus (generic Advair Diskus)
- Wixela Inhub (generic Advair Diskus)

**AND**

**1.2.2** ONE of the following:

**1.2.2.1** Patient is 5 years of age

**OR**

**1.2.2.2** Failure of Breyna or budesonide/formoterol (generic of Symbicort) confirmed by claims history or submitted medical records

**OR**

**1.2.2.3** History of intolerance or contraindication to Breyna or budesonide/formoterol (generic of Symbicort) (please specify intolerance or contraindication)

**OR**

**2 - ALL of the following:**

**2.1** Diagnosis of chronic obstructive pulmonary disease (COPD)

**AND**

**2.2** ONE of the following:

**2.2.1** Failure of ONE of the following confirmed by claims history or submitted medical records

- fluticasone propionate/salmeterol diskus (generic Advair Diskus)
- Wixela Inhub (generic Advair Diskus)

**OR**

**2.2.2** History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- fluticasone propionate/salmeterol diskus (generic Advair Diskus)
- Wixela Inhub (generic Advair Diskus)

**AND**

**2.3** ONE of the following:

**2.3.1** Failure of Breyna or budesonide/formoterol (generic of Symbicort) confirmed by claims history or submitted medical records

**OR**

**2.3.2** History of intolerance or contraindication to Breyna or budesonide/formoterol (generic of Symbicort) (please specify intolerance or contraindication)

Product Name: Advair HFA, Fluticasone-salmeterol (authorized generic of Advair HFA), Dulera, AirDuo Digihaler, AirDuo Respiclick \*

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Prior Authorization |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1 - Diagnosis of asthma</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>2 - ONE of the following:</b></p> <p><b>2.1</b> Failure of ONE of the following confirmed by claims history or submitted medical records:</p> <ul style="list-style-type: none"> <li>• fluticasone/salmeterol (authorized generic of AirDuo Resplick)</li> <li>• fluticasone propionate/salmeterol diskus (generic Advair Diskus)</li> <li>• Wixela Inhub (generic Advair Diskus)</li> </ul> <p style="text-align: center;"><b>OR</b></p> <p><b>2.2</b> History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication):</p> <ul style="list-style-type: none"> <li>• fluticasone/salmeterol (authorized generic of AirDuo Resplick)</li> <li>• fluticasone propionate/salmeterol diskus (generic Advair Diskus)</li> <li>• Wixela Inhub (generic Advair Diskus)</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>3 - ONE of the following:</b></p> <p><b>3.1</b> Failure of BOTH of the following confirmed by claims history or submitted medical records:</p> <ul style="list-style-type: none"> <li>• Breyna or budesonide/formoterol (generic of Symbicort)</li> <li>• fluticasone/vilanterol (authorized generic of Breo Ellipta)</li> </ul> <p style="text-align: center;"><b>OR</b></p> |                     |

**3.2** History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- Breyna or budesonide/formoterol (generic of Symbicort)
- fluticasone/vilanterol (authorized generic of Breo Ellipta)

Notes

\*Policy applies to Brand Necessary requests

Product Name: Brand Symbicort, Brand Advair Diskus\*

Approval Length

12 month(s)

Guideline Type

Prior Authorization

### Approval Criteria

**1** - All of the following:

**1.1** Diagnosis of asthma

**AND**

**1.2** ONE of the following:

**1.2.1** BOTH of the following:

**1.2.1.1** Patient is less than 12 years of age

**AND**

**1.2.1.2** ONE of the following:

**1.2.1.2.1** Failure of Breyna or budesonide/formoterol (generic of Symbicort) confirmed by claims history or submitted medical records

**OR**

**1.2.1.2.2** History of intolerance or contraindication to Breyna or budesonide/formoterol (generic of Symbicort) (please specify intolerance or contraindication)

**OR**

**1.2.2** BOTH of the following:

**1.2.2.1** ONE of the following:

**1.2.2.1.1** Failure of ONE of the following confirmed by claims history or submitted medical records:

- fluticasone/salmeterol (authorized generic of AirDuo Respiclick)
- fluticasone propionate/salmeterol diskus (generic Advair Diskus)
- Wixela Inhub (generic Advair Diskus)

**OR**

**1.2.2.1.2** History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication):

- fluticasone/salmeterol (authorized generic of AirDuo Respiclick)
- fluticasone propionate/salmeterol diskus (generic Advair Diskus)
- Wixela Inhub (generic Advair Diskus)

**AND**

**1.2.2.2** ONE of the following:

**1.2.2.2.1** Failure of BOTH of the following confirmed by claims history or submitted medical records:

- Breyna or budesonide/formoterol (generic of Symbicort)
- fluticasone/vilanterol (authorized generic of Breo Ellipta)

**OR**

**1.2.2.2.2** History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- Breyna or budesonide/formoterol (generic of Symbicort)
- fluticasone/vilanterol (authorized generic of Breo Ellipta)

**OR**

**2 - ALL of the following:**

**2.1** Diagnosis of chronic obstructive pulmonary disease (COPD)

**AND**

**2.2** ONE of the following:

**2.2.1** Failure of ONE of the following confirmed by claims history or submitted medical records:

- fluticasone propionate/salmeterol diskus (generic Advair Diskus)
- Wixela Inhub (generic Advair Diskus)

**OR**

**2.2.2** History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- fluticasone propionate/salmeterol diskus (generic Advair Diskus)
- Wixela Inhub (generic Advair Diskus)

**AND**

**2.3** ONE of the following:

**2.3.1** Failure of BOTH of the following confirmed by claims history or submitted medical records:

- Breyna or budesonide/formoterol (generic of Symbicort)
- fluticasone/vilanterol (authorized generic of Breo Ellipta)

**OR**



**2.3.2** History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- Breyna or budesonide/formoterol (generic of Symbicort)
- fluticasone/vilanterol (authorized generic of Breo Ellipta)

Notes

\*Policy applies to Brand Necessary requests

Product Name: Breo Ellipta\*

Approval Length

12 month(s)

Guideline Type

Prior Authorization

### Approval Criteria

1 - BOTH of the following:

1.1 Diagnosis of asthma

**AND**

1.2 BOTH of the following:

1.2.1 ONE of the following:

1.2.1.1 Failure of ONE of the following confirmed by claims history or submitted medical records:

- fluticasone/salmeterol (authorized generic of AirDuo Respiclick)
- fluticasone propionate/salmeterol diskus (generic Advair Diskus)
- Wixela Inhub (generic Advair Diskus)

**OR**

1.2.1.2 History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication):

- fluticasone/salmeterol (authorized generic of AirDuo Respiclick)
- fluticasone propionate/salmeterol diskus (generic Advair Diskus)

- Wixela Inhub (generic Advair Diskus)

**AND**

**1.2.2** ONE of the following:

**1.2.2.1** Failure of BOTH of the following confirmed by claims history or submitted medical records:

- Breyna or budesonide/formoterol (generic of Symbicort)
- fluticasone/vilanterol (authorized generic of Breo Ellipta)

**OR**

**1.2.2.2** History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- Breyna or budesonide/formoterol (generic of Symbicort)
- fluticasone/vilanterol (authorized generic of Breo Ellipta)

**OR**

**2** - ALL of the following:

**2.1** Diagnosis of chronic obstructive pulmonary disease (COPD)

**AND**

**2.2** ONE of the following:

**2.2.1** Failure of ONE of the following confirmed by claims history or submitted medical records:

- fluticasone propionate/salmeterol diskus (generic Advair Diskus)
- Wixela Inhub (generic Advair Diskus)

**OR**

**2.2.2** History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- fluticasone propionate/salmeterol diskus (generic Advair Diskus)
- Wixela Inhub (generic Advair Diskus)

**AND**

**2.3** ONE of the following:

**2.3.1** Failure of BOTH of the following confirmed by claims history or submitted medical records:

- Breyna or budesonide/formoterol (generic of Symbicort)
- fluticasone/vilanterol (authorized generic of Breo Ellipta)

**OR**

**2.3.2** History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- Breyna or budesonide/formoterol (generic of Symbicort)
- fluticasone/vilanterol (authorized generic of Breo Ellipta)

|       |                                             |
|-------|---------------------------------------------|
| Notes | *Policy applies to Brand Necessary requests |
|-------|---------------------------------------------|

## 2 . Revision History

| Date      | Notes                                                                                                                                                                                                                                                                                                                                            |
|-----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 11/7/2025 | Combined formularies. Updated product name lists, where applicable . Expanded on COPD abbreviation. Minor cosmetic updates throughout guideline. Added age bypass for generic Breo Ellipta to mirror Breyna and generic Symbicort. Added Breyna and generic Symbicort bypass in generic Breo Ellipta section due to differences in FDA labeling. |

Idhifa



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-444202                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Guideline Name</b> | Idhifa                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Washington (ACUWA, ACUWAAHE, ACUWAC)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 12/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                     |                              |
|---------------------|------------------------------|
| Product Name:Idhifa |                              |
| Diagnosis           | Acute Myeloid Leukemia (AML) |
| Approval Length     | 12 month(s)                  |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                       |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of acute myeloid leukemia (AML)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - AML is IDH2 (isocitrate dehydrogenase 2) mutation-positive</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - ONE of the following:</p> <p><b>3.1</b> Disease is relapsed or refractory</p> <p style="text-align: center;"><b>OR</b></p> <p><b>3.2</b> Used as low-intensity treatment induction when not a candidate for intensive induction therapy</p> <p style="text-align: center;"><b>OR</b></p> <p><b>3.3</b> Used for consolidation therapy as continuation of low-intensity regimen used for induction</p> <p style="text-align: center;"><b>OR</b></p> <p><b>3.4</b> Used as follow-up after induction therapy following response to previous lower intensity therapy with the same regimen</p> |                       |

|                      |                              |
|----------------------|------------------------------|
| Product Name: Idhifa |                              |
| Diagnosis            | Acute Myeloid Leukemia (AML) |

|                                                                                                                   |                     |
|-------------------------------------------------------------------------------------------------------------------|---------------------|
| Approval Length                                                                                                   | 12 month(s)         |
| Therapy Stage                                                                                                     | Reauthorization     |
| Guideline Type                                                                                                    | Prior Authorization |
| <b>Approval Criteria</b><br><br>1 - Patient does not show evidence of progressive disease while on Idhifa therapy |                     |

|                                                                                                                                         |                           |
|-----------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Idhifa                                                                                                                     |                           |
| Diagnosis                                                                                                                               | NCCN Recommended Regimens |
| Approval Length                                                                                                                         | 12 month(s)               |
| Therapy Stage                                                                                                                           | Initial Authorization     |
| Guideline Type                                                                                                                          | Prior Authorization       |
| <b>Approval Criteria</b><br><br>1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium |                           |

|                                                                                                   |                           |
|---------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Idhifa                                                                               |                           |
| Diagnosis                                                                                         | NCCN Recommended Regimens |
| Approval Length                                                                                   | 12 month(s)               |
| Therapy Stage                                                                                     | Reauthorization           |
| Guideline Type                                                                                    | Prior Authorization       |
| <b>Approval Criteria</b><br><br>1 - Documentation of positive clinical response to Idhifa therapy |                           |

## 2 . Revision History

UnitedHealthcare Community Plan of New Jersey – Clinical Pharmacy Guidelines

| Date      | Notes                                                  |
|-----------|--------------------------------------------------------|
| 11/7/2025 | Combined formularies. No changes to clinical criteria. |

Ilaris



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-164637                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Guideline Name</b> | Ilaris                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 3/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                     |                                                |
|---------------------|------------------------------------------------|
| Product Name:Ilaris |                                                |
| Diagnosis           | Cryopyrin-Associated Periodic Syndromes (CAPS) |
| Approval Length     | 12 month(s)                                    |
| Therapy Stage       | Initial Authorization                          |
| Guideline Type      | Prior Authorization                            |



**Approval Criteria**

**1** - Diagnosis of ONE of the following:

- Familial cold autoinflammatory syndrome (FCAS)
- Muckle-Wells Syndrome (MWS)

**AND**

**2** - Diagnosis is made by, or in consultation with, a rheumatologist or immunologist with expertise in the diagnosis of FCAS and MWS

|                                                                                                                                                                                                                                                                                                                                                                |                                                |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|
| Product Name:Ilaris                                                                                                                                                                                                                                                                                                                                            |                                                |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                      | Cryopyrin-Associated Periodic Syndromes (CAPS) |
| Approval Length                                                                                                                                                                                                                                                                                                                                                | 12 month(s)                                    |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                  | Reauthorization                                |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                 | Prior Authorization                            |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Patient is currently on Ilaris therapy for ONE of the following:</p> <ul style="list-style-type: none"> <li>• Familial cold autoinflammatory syndrome (FCAS)</li> <li>• Muckle-Wells Syndrome (MWS)</li> </ul> <p><b>AND</b></p> <p><b>2</b> - Documentation of positive clinical response to Ilaris therapy</p> |                                                |

|                     |                                                                           |
|---------------------|---------------------------------------------------------------------------|
| Product Name:Ilaris |                                                                           |
| Diagnosis           | Tumor Necrosis Factor (TNF) Receptor-Associated Periodic Syndrome (TRAPS) |
| Approval Length     | 12 month(s)                                                               |

|                                                                                                                                                                                                                                                                                                                                   |                       |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                                                                                                                                                                                                                                                                     | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                    | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of tumor necrosis factor (TNF) receptor-associated periodic syndrome (TRAPS)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Diagnosis is made by, or in consultation with, a rheumatologist or immunologist with expertise in the diagnosis of TRAPS</p> |                       |

|                                                                                                                                                                                                                                                                                                                                                                 |                                                                           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------|
| Product Name:Ilaris                                                                                                                                                                                                                                                                                                                                             |                                                                           |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                       | Tumor Necrosis Factor (TNF) Receptor-Associated Periodic Syndrome (TRAPS) |
| Approval Length                                                                                                                                                                                                                                                                                                                                                 | 12 month(s)                                                               |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                   | Reauthorization                                                           |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                  | Prior Authorization                                                       |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Patient is currently on Ilaris therapy for tumor necrosis factor (TNF) receptor-associated periodic syndrome (TRAPS)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Documentation of positive clinical response to Ilaris therapy, defined as a decrease in frequency or severity of attacks</p> |                                                                           |

|                     |                                                                                      |
|---------------------|--------------------------------------------------------------------------------------|
| Product Name:Ilaris |                                                                                      |
| Diagnosis           | Hyperimmunoglobulin D (Hyper-IgD) Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD) |
| Approval Length     | 12 month(s)                                                                          |

|                                                                                                                                                                                                                                                                                                                                                                                                                                    |                       |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                      | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                     | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of ONE of the following</p> <ul style="list-style-type: none"> <li>Hyperimmunoglobulin D (Hyper-IgD) Syndrome (HIDS)</li> <li>Mevalonate Kinase Deficiency (MKD)</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Diagnosis is made by, or in consultation with, a rheumatologist or immunologist with expertise in the diagnosis of HIDS or MKD</p> |                       |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                      |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|
| Product Name: Ilaris                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                      |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Hyperimmunoglobulin D (Hyper-IgD) Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD) |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                             | 12 month(s)                                                                          |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                               | Reauthorization                                                                      |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                              | Prior Authorization                                                                  |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Patient is currently on Ilaris therapy for ONE of the following:</p> <ul style="list-style-type: none"> <li>Hyperimmunoglobulin D (Hyper-IgD) Syndrome (HIDS)</li> <li>Mevalonate Kinase Deficiency (MKD)</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Documentation of positive clinical response to Ilaris therapy, defined as a decrease in frequency or severity of attacks</p> |                                                                                      |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                    |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|
| Product Name:Ilaris                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                    |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Familial Mediterranean Fever (FMF) |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 12 month(s)                        |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Initial Authorization              |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Prior Authorization                |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of Familial Mediterranean Fever (FMF)</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Diagnosis is made by, or in consultation with, a rheumatologist or immunologist with expertise in the diagnosis of FMF</p> <p style="text-align: center;"><b>AND</b></p> <p>3 - ONE of the following:</p> <p>3.1 Failure to colchicine as confirmed by claims history or submission of medical records</p> <p style="text-align: center;"><b>OR</b></p> <p>3.2 History of contraindication or intolerance to colchicine (please specify contraindication or intolerance)</p> |                                    |

|                     |                                    |
|---------------------|------------------------------------|
| Product Name:Ilaris |                                    |
| Diagnosis           | Familial Mediterranean Fever (FMF) |
| Approval Length     | 12 month(s)                        |
| Therapy Stage       | Reauthorization                    |
| Guideline Type      | Prior Authorization                |
|                     |                                    |

**Approval Criteria**

**1** - Patient is currently on Ilaris therapy for Familial Mediterranean Fever (FMF)

**AND**

**2** - Documentation of positive clinical response to Ilaris therapy, defined by a decrease in index disease flare or normalization of CRP (C-reactive protein)

**Product Name:Ilaris**

|                 |                                               |
|-----------------|-----------------------------------------------|
| Diagnosis       | Systemic Juvenile Idiopathic Arthritis (SJIA) |
| Approval Length | 12 month(s)                                   |
| Therapy Stage   | Initial Authorization                         |
| Guideline Type  | Prior Authorization                           |

**Approval Criteria**

**1** - Diagnosis of systemic juvenile idiopathic arthritis (SJIA)

**AND**

**2** - Diagnosis is made by, or in consultation with, a rheumatologist or immunologist with expertise in the diagnosis of SJIA

**AND**

**3** - Patient is NOT receiving Ilaris in combination with a targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab), Xeljanz (tofacitinib)]

**Product Name:Ilaris**

|                 |                                               |
|-----------------|-----------------------------------------------|
| Diagnosis       | Systemic Juvenile Idiopathic Arthritis (SJIA) |
| Approval Length | 12 month(s)                                   |
| Therapy Stage   | Reauthorization                               |

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Prior Authorization |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Patient is currently on Ilaris therapy for systemic juvenile idiopathic arthritis (SJIA)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Documentation of positive clinical response to Ilaris therapy</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Patient is not receiving Ilaris in combination with a targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab), Xeljanz (tofacitinib)]</p> |                     |

| Product Name:Ilaris                                                                                                                                                                                                                                                                                                                                |                                                      |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------|
| Diagnosis                                                                                                                                                                                                                                                                                                                                          | Still's Disease [Adult-Onset Still's Disease (AOSD)] |
| Approval Length                                                                                                                                                                                                                                                                                                                                    | 12 month(s)                                          |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                      | Initial Authorization                                |
| Guideline Type                                                                                                                                                                                                                                                                                                                                     | Prior Authorization                                  |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of Adult Onset Still's Disease (AOSD)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Diagnosis is made by, or in consultation with, a rheumatologist or immunologist with expertise in the diagnosis of Still's Disease</p> <p style="text-align: center;"><b>AND</b></p> |                                                      |

**3** - Patient is not receiving Ilaris in combination with a targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab), Xeljanz (tofacitinib)]

**Product Name:Ilaris**

|                 |                                                      |
|-----------------|------------------------------------------------------|
| Diagnosis       | Still's Disease [Adult-Onset Still's Disease (AOSD)] |
| Approval Length | 12 month(s)                                          |
| Therapy Stage   | Reauthorization                                      |
| Guideline Type  | Prior Authorization                                  |

**Approval Criteria**

**1** - Patient is currently on Ilaris therapy for Adult Onset Still's Disease (AOSD)

**AND**

**2** - Documentation of positive clinical response to Ilaris therapy

**AND**

**3** - Patient is not receiving Ilaris in combination with a targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab), Xeljanz (tofacitinib)]

**Product Name:Ilaris**

|                 |                     |
|-----------------|---------------------|
| Diagnosis       | Gout Flare          |
| Approval Length | 12 Week(s)          |
| Guideline Type  | Prior Authorization |

**Approval Criteria**

**1** - Diagnosis of a gout flare

**AND**

**2 - ONE of the following:**

**2.1** History of failure to BOTH of the following confirmed by claims history or submission of medical records:

- Colchicine
- Non-steroidal anti-inflammatory drugs (NSAIDs)

**OR**

**2.2** History of contraindication or intolerance to BOTH of the following (please specify contraindication or intolerance):

- Colchicine
- Non-steroidal anti-inflammatory drugs (NSAIDs)

**AND**

**3 - Provider attests that the patient is not an appropriate candidate for systemic corticosteroids**

**AND**

**4 - Prescribed by one of the following:**

- Rheumatologist
- Nephrologist

**AND**

**5 - The patient has not received Ilaris in the past 12 weeks**

## **2 . Revision History**



UnitedHealthcare Community Plan of New Jersey – Clinical Pharmacy Guidelines

| Date     | Notes                                                |
|----------|------------------------------------------------------|
| 2/3/2025 | Updated formularies. Updated concurrent use criteria |

Ilumya



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-182195                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Guideline Name</b> | Ilumya                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 4/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                     |                       |
|---------------------|-----------------------|
| Product Name:Ilumya |                       |
| Approval Length     | 12 month(s)           |
| Therapy Stage       | Initial Authorization |
| Guideline Type      | Prior Authorization   |
|                     |                       |

## **Approval Criteria**

**1** - Diagnosis of chronic moderate to severe plaque psoriasis

**AND**

**2** - Patient is NOT receiving Ilumya in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

**AND**

**3** - Prescribed by, or in consultation with, a dermatologist

**AND**

**4** - One of the following:

**4.1** Patient is currently on Ilumya therapy as confirmed by claims history or submission of medical records

**OR**

**4.2** BOTH of the following:

**4.2.1** ONE of the following:

**4.2.1.1** Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of plaque psoriasis as confirmed by claims history or submission of medical records [e.g., Cimzia (certolizumab), adalimumab, Otezla (apremilast), Skyrizi (risankizumab-rzaa), ustekinumab, Tremfya (guselkumab), Enbrel (etanercept)]

**OR**

**4.2.1.2** ALL of the following:

**4.2.1.2.1** Greater than or equal to 3% body surface area involvement, palmoplantar, facial, genital involvement, or severe scalp psoriasis

**AND**

**4.2.1.2.2** ONE of the following:

- Failure to ONE of the following topical therapy classes confirmed by claims history or submission of medical records: Corticosteroids (e.g., betamethasone, clobetasol, desonide), Vitamin D analogs (e.g., calcitriol, calcipotriene), Tazarotene, Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus), Anthralin, Coal tar
- History of intolerance or contraindication to ALL of the following topical therapy classes (please specify intolerance or contraindication): Corticosteroids (e.g., betamethasone, clobetasol, desonide), Vitamin D analogs (e.g., calcitriol, calcipotriene), Tazarotene, Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus), Anthralin, Coal tar

**AND**

**4.2.1.2.3** ONE of the following:

- Failure to a 3 month trial of methotrexate at the maximally indicated dose confirmed by claims history or submission of medical records
- History of intolerance or contraindication to methotrexate (please specify intolerance or contraindication)

**AND**

**4.2.2** ONE of the following:

**4.2.2.1** Failure to TWO of the following preferred products as confirmed by claims history or submitted medical records

- One of the preferred adalimumab products\*
- Enbrel (etanercept)
- One of the preferred ustekinumab products\*

**OR**

**4.2.2.2** History of intolerance or contraindication to ALL of the following preferred products (please specify intolerance or contraindication)

|                                                                                                                                                                                    |                              |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|
| <ul style="list-style-type: none"> <li>• One of the preferred adalimumab products*</li> <li>• Enbrel (etanercept)</li> <li>• One of the preferred ustekinumab products*</li> </ul> |                              |
| Notes                                                                                                                                                                              | *See PDL links in Background |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                     |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Ilumya                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                     |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | 12 month(s)         |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p>1 - Documentation of positive clinical response to Ilumya therapy</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Patient is NOT receiving Ilumya in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]</p> |                     |

## 2 . Background

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Benefit/Coverage/Program Information</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <p><b>PDL Links</b></p> <p>CO: <a href="https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html</a></p> <p>HI: <a href="https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html</a></p> |

|                                                                                                                                                                                                                                                                                   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| MD: <a href="https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-cp-pharmacy.html</a>                               |
| NJ: <a href="https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html</a>                           |
| NM: <a href="https://www.uhcprovider.com/en/health-plans-by-state/new-mexico-health-plans/nm-comm-plan-home/nm-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/new-mexico-health-plans/nm-comm-plan-home/nm-cp-pharmacy.html</a>                           |
| NY: <a href="https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html</a>                               |
| PA: <a href="https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP">https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP</a> |
| RI: <a href="https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html</a>                       |

### 3 . Revision History

| Date      | Notes                                                                                                                                                                                      |
|-----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 2/21/2025 | Updated formularies. Updated criteria to add ST through two preferred targeted immunomodulators. Updated safety check language. Removed reference to brand Stelara - replaced with generic |

Imbruvica



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-161243                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Guideline Name</b> | Imbruvica                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 1/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                        |                       |
|------------------------|-----------------------|
| Product Name:Imbruvica |                       |
| Diagnosis              | B-Cell Lymphoma       |
| Approval Length        | 12 month(s)           |
| Therapy Stage          | Initial Authorization |
| Guideline Type         | Prior Authorization   |

### **Approval Criteria**

**1 - BOTH of the following:**

**1.1** Diagnosis of mantle cell lymphoma (MCL)

**AND**

**1.2** ONE of the following:

**1.2.1** Patient has received at least one prior therapy for MCL

**OR**

**1.2.2** Used in pre-treatment therapy in combination with Rituxan (rituximab) to limit the number of cycles with RHyperCVAD (rituximab, cyclophosphamide, vincristine, doxorubicin, and dexamethasone) regimen

**OR**

**2 - Diagnosis of ONE of the following:**

- Chronic Lymphocytic Leukemia (CLL)
- Small Lymphocytic Lymphoma (SLL)

**OR**

**3 - BOTH of the following:**

**3.1** Diagnosis of ONE of the following:

- Diffuse large B-cell lymphoma [non-GCB DLBCL (non-germinal center B-cell diffuse large B-cell) and non-candidate for transplant]
- Human Immunodeficiency Virus (HIV)-related B-cell lymphoma
- Post-transplant lymphoproliferative disorders
- Histologic transformation to diffuse large B-cell lymphoma
- Hairy cell leukemia
- Nodal or splenic marginal zone lymphoma (MZL)



- Extranodal marginal zone lymphoma (EMZL) of the stomach
- Extranodal marginal zone lymphoma (EMZL) of nongastric sites (noncutaneous)
- High grade B-cell lymphoma

**AND**

**3.2** Used as second-line or a subsequent therapy

|                                                                                                                    |                                                            |
|--------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------|
| Product Name:Imbruvica                                                                                             |                                                            |
| Diagnosis                                                                                                          | Waldenström's Macroglobulinemia/Lymphoplasmacytic Lymphoma |
| Approval Length                                                                                                    | 12 month(s)                                                |
| Therapy Stage                                                                                                      | Initial Authorization                                      |
| Guideline Type                                                                                                     | Prior Authorization                                        |
| <b>Approval Criteria</b><br><br><b>1</b> - Diagnosis of Waldenström's Macroglobulinemia/Lymphoplasmacytic Lymphoma |                                                            |

|                                                                                                                                                                                             |                       |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Imbruvica                                                                                                                                                                      |                       |
| Diagnosis                                                                                                                                                                                   | Primary CNS Lymphoma  |
| Approval Length                                                                                                                                                                             | 12 month(s)           |
| Therapy Stage                                                                                                                                                                               | Initial Authorization |
| Guideline Type                                                                                                                                                                              | Prior Authorization   |
| <b>Approval Criteria</b><br><br><b>1</b> - Diagnosis of primary central nervous system (CNS) lymphoma<br><br><p style="text-align: center;"><b>AND</b></p> <b>2</b> - ONE of the following: |                       |

**2.1** Used as second-line or a subsequent therapy

**OR**

**2.2** Used as induction therapy if the patient is unsuitable or intolerant to high-dose methotrexate

| Product Name:Imbruvica                                                                                                  |                                                                                                   |
|-------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------|
| Diagnosis                                                                                                               | B-Cell Lymphoma, Waldenström's Macroglobulinemia/Lymphoplasmacytic Lymphoma, Primary CNS Lymphoma |
| Approval Length                                                                                                         | 12 month(s)                                                                                       |
| Therapy Stage                                                                                                           | Reauthorization                                                                                   |
| Guideline Type                                                                                                          | Prior Authorization                                                                               |
| <b>Approval Criteria</b><br><b>1</b> - Patient does not show evidence of progressive disease while on Imbruvica therapy |                                                                                                   |

| Product Name:Imbruvica                                                                                  |                                   |
|---------------------------------------------------------------------------------------------------------|-----------------------------------|
| Diagnosis                                                                                               | Chronic Graft Versus Host Disease |
| Approval Length                                                                                         | 12 month(s)                       |
| Therapy Stage                                                                                           | Initial Authorization             |
| Guideline Type                                                                                          | Prior Authorization               |
| <b>Approval Criteria</b><br><b>1</b> - Diagnosis of chronic graft versus host disease<br><br><b>AND</b> |                                   |

**2** - History of failure of at least one other systemic therapy [e.g., corticosteroids, mycophenolate, etc.] as confirmed by claims history or submission of medical records

|                                                                                                                            |                                   |
|----------------------------------------------------------------------------------------------------------------------------|-----------------------------------|
| Product Name:Imbruvica                                                                                                     |                                   |
| Diagnosis                                                                                                                  | Chronic Graft Versus Host Disease |
| Approval Length                                                                                                            | 12 month(s)                       |
| Therapy Stage                                                                                                              | Reauthorization                   |
| Guideline Type                                                                                                             | Prior Authorization               |
| <b>Approval Criteria</b><br><br><b>1</b> - Patient shows evidence of positive clinical response while on Imbruvica therapy |                                   |

|                                                                                                                                                |                          |
|------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|
| Product Name:Imbruvica                                                                                                                         |                          |
| Diagnosis                                                                                                                                      | NCCN Recommended Regimen |
| Approval Length                                                                                                                                | 12 month(s)              |
| Therapy Stage                                                                                                                                  | Initial Authorization    |
| Guideline Type                                                                                                                                 | Prior Authorization      |
| <b>Approval Criteria</b><br><br><b>1</b> - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium |                          |

|                        |                          |
|------------------------|--------------------------|
| Product Name:Imbruvica |                          |
| Diagnosis              | NCCN Recommended Regimen |
| Approval Length        | 12 month(s)              |
| Therapy Stage          | Reauthorization          |
| Guideline Type         | Prior Authorization      |

**Approval Criteria**

1 - Documentation of positive clinical response to Imbruvica therapy

**2 . Revision History**

| Date       | Notes                                                      |
|------------|------------------------------------------------------------|
| 11/25/2024 | Added rituximab to RHyperCVAD and minor formatting changes |

Imcivree



## Prior Authorization Guideline

|                       |                                                                                                         |
|-----------------------|---------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-144221                                                                                               |
| <b>Guideline Name</b> | Imcivree                                                                                                |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>Medicaid - Community &amp; State New Jersey (PSI2300)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 4/1/2024 |
|-----------------|----------|

## 1 . Criteria

|                                                                                                                                                                                                                                                                                                                                                           |                       |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Imcivree                                                                                                                                                                                                                                                                                                                                     |                       |
| Approval Length                                                                                                                                                                                                                                                                                                                                           | 6 month(s)            |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                             | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                            | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - ONE of the following:</p> <p><b>1.1</b> Diagnosis of obesity is due to pro-opiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) gene deficiency confirmed with genetic testing interpreted as pathogenic, likely pathogenic, or of uncertain significance</p> |                       |

**OR**

**1.2** Diagnosis of obesity due to Bardet-Biedl syndrome

**AND**

**2** - ONE of the following:

**2.1** Adult patient (18 years or older) with body mass index (BMI) greater than or equal to 30 kg/m<sup>2</sup>

**OR**

**2.2** Pediatric patient with weight greater than or equal to 95th percentile for age on growth chart assessment

**AND**

**3** - Patient is currently enrolled in or has history of a weight loss management program

|                                                                                                                                                                                                                                                                                                |                     |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Imcivree                                                                                                                                                                                                                                                                          |                     |
| Approval Length                                                                                                                                                                                                                                                                                | 12 month(s)         |
| Therapy Stage                                                                                                                                                                                                                                                                                  | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                                                                 | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - ONE of the following:</p> <p><b>1.1</b> BOTH of the following:</p> <p><b>1.1.1</b> Diagnosis of obesity due to pro-opiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) gene deficiency</p> |                     |

**AND**

**1.1.2** ONE of the following:

**1.1.2.1** If on therapy for less than 12 months, documentation of a positive clinical response to Imcivree therapy defined as weight loss greater than or equal to 5% of baseline body weight or 5% of baseline body mass index (BMI)

**OR**

**1.1.2.2** If on therapy for greater than or equal to 12 months, documentation of a positive clinical response to Imcivree therapy defined as greater than or equal to 10% weight loss from baseline

**OR**

**1.2** BOTH of the following:

**1.2.1** Diagnosis of obesity and Bardet-Biedl syndrome

**AND**

**1.2.2** ONE of the following:

**1.2.2.1** For pediatric patients, documentation of a positive clinical response to Imcivree therapy defined as weight loss greater than or equal to 5% of baseline BMI

**OR**

**1.2.2.2** For adult patients 18 years and older, documentation of a positive clinical response to Imcivree therapy defined as weight loss greater than or equal to 5% of baseline body weight

## **2 . Revision History**

UnitedHealthcare Community Plan of New Jersey – Clinical Pharmacy Guidelines

| Date      | Notes        |
|-----------|--------------|
| 3/25/2024 | New program. |



Inbrija



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-216281                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Guideline Name</b> | Inbrija                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 5/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                      |                       |
|----------------------|-----------------------|
| Product Name:Inbrija |                       |
| Approval Length      | 12 month(s)           |
| Therapy Stage        | Initial Authorization |
| Guideline Type       | Prior Authorization   |

**Approval Criteria**

**1** - Diagnosis of Parkinson's disease

**AND**

**2** - Inbrija will be used as intermittent treatment for OFF episodes

**AND**

**3** - Prescribed by, or in consultation with, a neurologist or specialist in the treatment of Parkinson's disease

**AND**

**4** - Patient is currently on a stable dose of a carbidopa/levodopa-containing medication and will continue receiving treatment with a carbidopa/levodopa-containing medication while on therapy

**AND**

**5** - Patient continues to experience greater than or equal to 2 hours of OFF time per day despite optimal management of carbidopa/levodopa therapy including BOTH of the following:

- Taking carbidopa/levodopa on an empty stomach or at least one half-hour or more before or one hour after a meal or avoidance of high protein diet
- Dose and dosing interval optimization

**AND**

**6** - ONE of the following:

**6.1** Failure to TWO anti-Parkinson's disease therapies from the following adjunctive pharmacotherapy classes confirmed by claims history or submission of medical records (trial must be from two different classes):

- Dopamine agonists (e.g., pramipexole, ropinirole)
- Catechol-O-methyl transferase (COMT) inhibitors (e.g., entacapone)
- Monoamine oxidase (MAO) B inhibitors (e.g., selegiline)

**OR**

**6.2** History of contraindication or intolerance to ALL anti-Parkinson's disease therapies from the following adjunctive pharmacotherapy classes (please specify intolerance or contraindication):

- Dopamine agonists (e.g., pramipexole, ropinirole)
- Catechol-O-methyl transferase (COMT) inhibitors (e.g., entacapone)
- Monoamine oxidase (MAO) B inhibitors (e.g., selegiline)

|                                                                                                                                                                                                                                                               |                     |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Inbrija                                                                                                                                                                                                                                          |                     |
| Approval Length                                                                                                                                                                                                                                               | 12 month(s)         |
| Therapy Stage                                                                                                                                                                                                                                                 | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                                | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p>1 - Documentation of positive clinical response to Inbrija therapy</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Patient will continue to receive treatment with a carbidopa/levodopa-containing medication</p> |                     |

## 2 . Revision History

| Date      | Notes                                                                                                             |
|-----------|-------------------------------------------------------------------------------------------------------------------|
| 3/18/2025 | Combined formularies. Minor update to required value section in criterion 5, but no changes to clinical criteria. |

Ingrezza



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-164976                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Guideline Name</b> | Ingrezza                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 3/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                       |                       |
|-----------------------|-----------------------|
| Product Name:Ingrezza |                       |
| Diagnosis             | Tardive Dyskinesia    |
| Approval Length       | 12 month(s)           |
| Therapy Stage         | Initial Authorization |
| Guideline Type        | Prior Authorization   |

**Approval Criteria**

1 - Diagnosis of moderate to severe tardive dyskinesia

**AND**

2 - ONE of the following:

**2.1** Patient has persistent symptoms of tardive dyskinesia despite a trial of dose reduction, tapering, or discontinuation of the offending medication

**OR**

**2.2** Patient is not a candidate for a trial of dose reduction, tapering, or discontinuation of the offending medication

**AND**

3 - Prescribed by or in consultation with ONE of the following:

- Neurologist
- Psychiatrist

|                                                                                                     |                                             |
|-----------------------------------------------------------------------------------------------------|---------------------------------------------|
| Product Name: Ingrezza                                                                              |                                             |
| Diagnosis                                                                                           | Chorea associated with Huntington's Disease |
| Approval Length                                                                                     | 12 month(s)                                 |
| Therapy Stage                                                                                       | Initial Authorization                       |
| Guideline Type                                                                                      | Prior Authorization                         |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of chorea associated with Huntington's disease</p> |                                             |

**AND**

**2** - Prescribed by or in consultation with ONE of the following:

- Neurologist
- Psychiatrist

|                                                                                                            |                                                                 |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------|
| Product Name:Ingrezza                                                                                      |                                                                 |
| Diagnosis                                                                                                  | Tardive Dyskinesia, Chorea associated with Huntington's Disease |
| Approval Length                                                                                            | 12 month(s)                                                     |
| Therapy Stage                                                                                              | Reauthorization                                                 |
| Guideline Type                                                                                             | Prior Authorization                                             |
| <b>Approval Criteria</b><br><br><b>1</b> - Documentation of positive clinical response to Ingrezza therapy |                                                                 |

## 2 . Revision History

| Date      | Notes                             |
|-----------|-----------------------------------|
| 2/11/2025 | Updated formularies. Updated GPIs |

Inhaled Corticosteroids



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-375650                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Guideline Name</b> | Inhaled Corticosteroids                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 10/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                                                                                                                                                                                               |                     |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Alvesco, ArmonAir Digihaler, Arnuity Ellipta, Fluticasone furoate ellipta, Flovent Diskus, Fluticasone propionate diskus, Brand Flovent HFA, Pulmicort Flexhaler, Qvar RediHaler |                     |
| Approval Length                                                                                                                                                                               | 12 month(s)         |
| Guideline Type                                                                                                                                                                                | Prior Authorization |
| <b>Approval Criteria</b>                                                                                                                                                                      |                     |

**1 - Diagnosis of asthma**

**AND**

**2 - ONE of the following:**

**2.1** Failure of BOTH of the following confirmed by claims history or submitted medical records:

- Fluticasone propionate HFA
- Asmanex HFA or Asmanex Twisthaler

**OR**

**2.2** History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- Fluticasone propionate HFA
- Asmanex HFA or Asmanex Twisthaler

## 2 . Revision History

| Date     | Notes                                                                                                                                        |
|----------|----------------------------------------------------------------------------------------------------------------------------------------------|
| 9/3/2025 | Updated formularies. Removed Asmanex HFA and Twisthaler. Updated GPIs. Removed brand from "Brand Fluticasone propionate HFA" per ops request |



Inlyta



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-432269                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Guideline Name</b> | Inlyta                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 12/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                      |                       |
|----------------------|-----------------------|
| Product Name: Inlyta |                       |
| Diagnosis            | Renal Cell Carcinoma  |
| Approval Length      | 12 month(s)           |
| Therapy Stage        | Initial Authorization |
| Guideline Type       | Prior Authorization   |

### Approval Criteria

1 - BOTH of the following:

1.1 Diagnosis of advanced renal cell carcinoma

**AND**

1.2 ONE of the following:

- Patient has failed one prior systemic therapy
- The requested medication will be used in combination with Bavencio (avelumab) or Keytruda (pembrolizumab)

**OR**

2 - Diagnosis of relapsed or stage IV renal cell carcinoma

|                                                                                                                                                                                                                                |                       |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Inlyta                                                                                                                                                                                                            |                       |
| Diagnosis                                                                                                                                                                                                                      | Thyroid Carcinoma     |
| Approval Length                                                                                                                                                                                                                | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                  | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                 | Prior Authorization   |
| <h3>Approval Criteria</h3> <p>1 - ONE of the following diagnoses:</p> <ul style="list-style-type: none"> <li>• Follicular Carcinoma</li> <li>• Oncocytic Carcinoma</li> <li>• Papillary Carcinoma</li> </ul> <p><b>AND</b></p> |                       |

**2** - Disease is ONE of the following:

- Recurrent and unresectable
- Persistent
- Metastatic

**AND**

**3** - Disease is not amenable to radioactive iodine treatment

|                                                                                                                                                                                                                                                               |                       |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Inlyta                                                                                                                                                                                                                                           |                       |
| Diagnosis                                                                                                                                                                                                                                                     | Salivary Gland Tumor  |
| Approval Length                                                                                                                                                                                                                                               | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                 | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of salivary gland tumor</p> <p><b>AND</b></p> <p><b>2</b> - Disease is ONE of the following:</p> <ul style="list-style-type: none"> <li>• Recurrent and unresectable</li> <li>• Metastatic</li> </ul> |                       |

|                     |                       |
|---------------------|-----------------------|
| Product Name:Inlyta |                       |
| Diagnosis           | Soft Tissue Sarcoma   |
| Approval Length     | 12 month(s)           |
| Therapy Stage       | Initial Authorization |
| Guideline Type      | Prior Authorization   |

**Approval Criteria**

**1** - Diagnosis of alveolar soft part sarcoma (ASPS)

**AND**

**2** - The requested medication will be used in combination with Keytruda (pembrolizumab)

Product Name:Inlyta

|                 |                       |
|-----------------|-----------------------|
| Diagnosis       | Thymic Carcinoma      |
| Approval Length | 12 month(s)           |
| Therapy Stage   | Initial Authorization |
| Guideline Type  | Prior Authorization   |

**Approval Criteria**

**1** - Diagnosis of Thymic Carcinoma

**AND**

**2** - ONE of the following:

- Used as first-line therapy for those who cannot tolerate first-line combination regimens
- Used as second-line therapy

**AND**

**3** - The requested medication will be used in combination with Bavencio (avelumab)

Product Name:Inlyta

|                                                                                                                          |                                                                                                      |
|--------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------|
| Diagnosis                                                                                                                | Renal Cell Carcinoma, Thyroid Carcinoma, Salivary Gland Tumor, Soft Tissue Sarcoma, Thymic Carcinoma |
| Approval Length                                                                                                          | 12 month(s)                                                                                          |
| Therapy Stage                                                                                                            | Reauthorization                                                                                      |
| Guideline Type                                                                                                           | Prior Authorization                                                                                  |
| <b>Approval Criteria</b><br><br><b>1</b> - Patient does not show evidence of progressive disease while on Inlyta therapy |                                                                                                      |

|                                                                                                                                                |                           |
|------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Inlyta                                                                                                                            |                           |
| Diagnosis                                                                                                                                      | NCCN Recommended Regimens |
| Approval Length                                                                                                                                | 12 month(s)               |
| Therapy Stage                                                                                                                                  | Initial Authorization     |
| Guideline Type                                                                                                                                 | Prior Authorization       |
| <b>Approval Criteria</b><br><br><b>1</b> - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium |                           |

|                                                                                                          |                           |
|----------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Inlyta                                                                                      |                           |
| Diagnosis                                                                                                | NCCN Recommended Regimens |
| Approval Length                                                                                          | 12 month(s)               |
| Therapy Stage                                                                                            | Reauthorization           |
| Guideline Type                                                                                           | Prior Authorization       |
| <b>Approval Criteria</b><br><br><b>1</b> - Documentation of positive clinical response to Inlyta therapy |                           |

## 2 . Revision History

| Date       | Notes                                                          |
|------------|----------------------------------------------------------------|
| 10/29/2025 | Combined formularies. Added new criteria for Thymic carcinoma. |

Inqovi



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-219310                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Guideline Name</b> | Inqovi                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Arizona (ACUAZ, ACUAZEC)</li> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Washington (ACUWA, ACUWAAHE, ACUWAC)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 5/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                      |                                |
|----------------------|--------------------------------|
| Product Name: Inqovi |                                |
| Diagnosis            | Myelodysplastic Syndrome (MDS) |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                       |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of myelodysplastic syndrome (e.g., previously treated and untreated, de novo and secondary MDS with the following French-American-British subtypes {refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, and chronic myelomonocytic leukemia [CMML]})</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Patient is intermediate-1, intermediate-2, or high-risk per the International Prognostic Scoring System (IPSS)</p> |                       |

|                                                                                                                                 |                                |
|---------------------------------------------------------------------------------------------------------------------------------|--------------------------------|
| Product Name:Inqovi                                                                                                             |                                |
| Diagnosis                                                                                                                       | Myelodysplastic Syndrome (MDS) |
| Approval Length                                                                                                                 | 12 month(s)                    |
| Therapy Stage                                                                                                                   | Reauthorization                |
| Guideline Type                                                                                                                  | Prior Authorization            |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Patient does not show evidence of progressive disease while on Inqovi therapy</p> |                                |

|                     |                           |
|---------------------|---------------------------|
| Product Name:Inqovi |                           |
| Diagnosis           | NCCN Recommended Regimens |
| Approval Length     | 12 month(s)               |
| Therapy Stage       | Initial Authorization     |
| Guideline Type      | Prior Authorization       |



**Approval Criteria**

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Inqovi

|           |                           |
|-----------|---------------------------|
| Diagnosis | NCCN Recommended Regimens |
|-----------|---------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                 |
|---------------|-----------------|
| Therapy Stage | Reauthorization |
|---------------|-----------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

1 - Documentation of positive clinical response to Inqovi therapy

## 2 . Revision History

| Date      | Notes                                                        |
|-----------|--------------------------------------------------------------|
| 3/20/2025 | Updated formularies. Removed CMML as it would fall under MDS |

Inrebic



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-135140                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Guideline Name</b> | Inrebic                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 1/1/2024 |
|-----------------|----------|

## 1 . Criteria

|                      |                       |
|----------------------|-----------------------|
| Product Name:Inrebic |                       |
| Diagnosis            | Myelofibrosis         |
| Approval Length      | 12 month(s)           |
| Therapy Stage        | Initial Authorization |
| Guideline Type       | Prior Authorization   |

**Approval Criteria**

**1** - Diagnosis of intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis

**AND**

**2** - One of the following:

**2.1** Failure to Jakafi (ruxolitinib) confirmed by claims history or submitted medical records

**OR**

**2.2** History of intolerance or contraindication to Jakafi (ruxolitinib) (please specify intolerance or contraindication)

**OR**

**2.3** Patient is currently on Inrebic therapy

|                                                                                                                                                                     |                     |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Inrebic                                                                                                                                                |                     |
| Diagnosis                                                                                                                                                           | Myelofibrosis       |
| Approval Length                                                                                                                                                     | 12 month(s)         |
| Therapy Stage                                                                                                                                                       | Reauthorization     |
| Guideline Type                                                                                                                                                      | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation that the patient has evidence of symptom improvement or reduction in spleen volume while on Inrebic</p> |                     |

|                      |
|----------------------|
| Product Name:Inrebic |
|----------------------|

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                            |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Myeloid/Lymphoid Neoplasms |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | 12 month(s)                |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Initial Authorization      |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Prior Authorization        |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of lymphoid, myeloid, or mixed lineage neoplasms with eosinophilia</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Patient has a JAK2 (Janus kinase 2) rearrangement</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - ONE of the following:</p> <p><b>3.1</b> Failure to Jakafi (ruxolitinib) confirmed by claims history or submitted medical records</p> <p style="text-align: center;"><b>OR</b></p> <p><b>3.2</b> History of intolerance or contraindication to Jakafi (ruxolitinib) (please specify intolerance or contraindication)</p> <p style="text-align: center;"><b>OR</b></p> <p><b>3.3</b> Patient is currently on Inrebic therapy</p> |                            |

|                      |                            |
|----------------------|----------------------------|
| Product Name:Inrebic |                            |
| Diagnosis            | Myeloid/Lymphoid Neoplasms |
| Approval Length      | 12 month(s)                |
| Therapy Stage        | Reauthorization            |
| Guideline Type       | Prior Authorization        |

**Approval Criteria**

1 - Patient does not show evidence of progressive disease while on Inrebic therapy

Product Name:Inrebic

|           |                           |
|-----------|---------------------------|
| Diagnosis | NCCN Recommended Regimens |
|-----------|---------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Inrebic

|           |                           |
|-----------|---------------------------|
| Diagnosis | NCCN Recommended Regimens |
|-----------|---------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                 |
|---------------|-----------------|
| Therapy Stage | Reauthorization |
|---------------|-----------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

1 - Documentation of positive clinical response to Inrebic therapy

## 2 . Revision History

| Date | Notes |
|------|-------|
|------|-------|

|            |                         |
|------------|-------------------------|
| 10/18/2023 | Removed RMHCO formulary |
|------------|-------------------------|



Insulin Pen Needles and Syringes



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-369238                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Guideline Name</b> | Insulin Pen Needles and Syringes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Arizona (ACUAZ, ACUAZEC)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Washington (ACUWA, ACUWAAHE, ACUWAC)</li> <li>• Medicaid - Community &amp; State Kansas (ACUKS, ACUKSC, ACUKSEC)</li> <li>• Medicaid - Community &amp; State Pennsylvania (ACUPA)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 9/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                      |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|
| Product Name:Non-preferred insulin pen needles and insulin syringes                                                                                                                                                                                                                                                                                                                                                                                         |                                      |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Non-Preferred                        |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                             | 12 month(s)                          |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                              | Prior Authorization                  |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - If the request is non-preferred*, history of failure to a preferred* Embecta insulin pen needle or syringe as confirmed by claims history or submission of medical records</p> <p style="text-align: center;"><b>OR</b></p> <p><b>2</b> - If the request is non-preferred*, physician has provided documentation as to why the patient is unable to use a preferred* Embecta product (document rationale)</p> |                                      |
| Notes                                                                                                                                                                                                                                                                                                                                                                                                                                                       | *PDL links are listed in Background. |

|                                                                                                                                                                    |                                                                             |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| Product Name:All insulin pen needles and insulin syringes                                                                                                          |                                                                             |
| Diagnosis                                                                                                                                                          | Requests exceeding 6 pen needles or syringes per day*                       |
| Approval Length                                                                                                                                                    | 12 month(s)                                                                 |
| Guideline Type                                                                                                                                                     | Quantity Limit                                                              |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Physician confirmation that the patient requires a greater quantity because of more frequent delivery of insulin</p> |                                                                             |
| Notes                                                                                                                                                              | *The quantity limit for both pen needles and syringes is 6 of each per day. |

## 2 . Background



## Benefit/Coverage/Program Information

### PDL links

**CO:** <https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html>

**HI:** <https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html>

**MD:** <https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-cp-pharmacy.html>

**NJ:** <https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html>

**NY/NY EPP:** <https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html>

**PA:** <https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP>

**RI:** <https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html>

**AZ:** <https://www.uhcprovider.com/en/health-plans-by-state/arizona-health-plans/az-comm-plan-home/az-cp-pharmacy.html?rfid=UHCCP>

**KS:** <https://www.uhcprovider.com/en/health-plans-by-state/kansas-health-plans/ks-comm-plan-home/ks-cp-pharmacy.html>

**NM:** <https://www.uhcprovider.com/en/health-plans-by-state/new-mexico-health-plans/nm-comm-plan-home/nm-cp-pharmacy.html>

**VA:** <https://www.uhcprovider.com/en/health-plans-by-state/virginia-health-plans/va-comm-plan-home/va-cp-pharmacy.html>

**WA:** <https://www.uhcprovider.com/en/health-plans-by-state/washington-health-plans/wa-comm-plan-home/wa-cp-pharmacy.html>

**NE:** <https://www.uhcprovider.com/en/health-plans-by-state/nebraska-health-plans/ne-comm-plan-home/ne-cp-pharmacy.html>

**IN:** <https://www.uhcprovider.com/en/health-plans-by-state/indiana-health-plans/in-comm-plan-home/in-cp-pharmacy.html>

### 3 . Revision History

| Date      | Notes                         |
|-----------|-------------------------------|
| 8/18/2025 | Updated formularies to add IN |

Insulins



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-382187                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Guideline Name</b> | Insulins                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 10/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                                                                                                 |                     |
|-------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Admelog vial, Apidra vial, Humalog 100U/ml vial, Insulin Aspart vial, Lyumjev vial |                     |
| Approval Length                                                                                 | 12 month(s)         |
| Guideline Type                                                                                  | Prior Authorization |
| Approval Criteria                                                                               |                     |

**1 - ONE of the following:**

**1.1** Failure to insulin lispro vial confirmed by claims history or submission of medical records

**OR**

**1.2** History of contraindication or intolerance to insulin lispro vial (please specify intolerance or contraindication)

**Product Name:**Novolog vial, Fiasp vial, Merilog vial

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

**1 - ONE of the following:**

**1.1** Failure to BOTH of the following confirmed by claims history or submission of medical records:

- insulin lispro vial
- Insulin Aspart vial

**OR**

**1.2** History of contraindication or intolerance to BOTH of the following (please specify intolerance or contraindication):

- insulin lispro vial
- Insulin Aspart vial

**Product Name:**Novolog Mix 70/30 vial, Novolog Mix 70/30 Relion vial

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

1 - ONE of the following:

1.1 Failure to Insulin Aspart mix vial confirmed by claims history or submission of medical records

**OR**

1.2 History of contraindication or intolerance to Insulin Aspart mix vial (please specify intolerance or contraindication)

Product Name:Humalog Mix 75/25 vial

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

1 - ONE of the following:

1.1 Failure to Insulin lispro protamine/insulin lispro Kwikpen 75/25 100U/ML confirmed by claims history or submission of medical records

**OR**

1.2 History of contraindication or intolerance to Insulin lispro protamine/insulin lispro Kwikpen 75/25 100U/ML (please specify intolerance or contraindication)

Product Name:Humulin R U-500 vial, Humulin R U-500 Kwikpen

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

1 - Patient requires more than 200 units of insulin per day

Product Name: Insulin Lispro Kwikpen, Insulin Lispro Junior Kwikpen

Approval Length 12 month(s)

Guideline Type Prior Authorization

**Approval Criteria**

1 - ONE of the following:

1.1 A visual impairment that prevents the patient from using a vial and syringe to accurately draw up the dose of insulin

**OR**

1.2 A physical disability or handicap that prevents the patient from using a vial and syringe to draw up the dose and administer the insulin

**OR**

1.3 History of failure to insulin lispro vial as demonstrated by poorly controlled diabetes based on hemoglobin A1c

**OR**

1.4 The patient is unable to use the vial dosage form of the drug due to documented poor compliance with vials and syringes resulting in poorly controlled diabetes based on hemoglobin A1c

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                     |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name: Apidra Solostar pen, Humalog cartridge, Humalog Kwikpen, Humalog Junior Kwikpen, Insulin Aspart Penfill, Insulin Aspart Flexpen, Admelog Solostar pen, Lyumjev Kwikpen, Merilog Solostar                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                     |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | 12 month(s)         |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1 - ONE of the following:</b></p> <p><b>1.1 One of the following:</b></p> <p><b>1.1.1</b> Failure to insulin lispro vial confirmed by claims history or submission of medical records</p> <p style="text-align: center;"><b>OR</b></p> <p><b>1.1.2</b> History of contraindication or intolerance to insulin lispro vial (please specify intolerance or contraindication)</p> <p style="text-align: center;"><b>OR</b></p> <p><b>1.2 ONE of the following:</b></p> <p><b>1.2.1</b> A visual impairment that prevents the patient from using a vial and syringe to accurately draw up the dose of insulin</p> <p style="text-align: center;"><b>OR</b></p> <p><b>1.2.2</b> A physical disability or handicap that prevents the patient from using a vial and syringe to draw up the dose and administer the insulin</p> <p style="text-align: center;"><b>OR</b></p> <p><b>1.2.3</b> The patient is unable to use the vial dosage form of the drug due to documented poor compliance with vials and syringes resulting in poorly controlled diabetes based on hemoglobin A1c</p> |                     |

**AND**

**2 - ONE of the following:**

**2.1** Failure to insulin lispro Kwikpen confirmed by claims history or submission of medical records

**OR**

**2.2** History of contraindication or intolerance to insulin lispro Kwikpen (please specify intolerance or contraindication)

Product Name: Humalog Tempo Pen, Lyumjev Tempo Pen

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

**1 - BOTH of the following:**

**1.1 ONE of the following:**

**1.1.1** Failure to insulin lispro Kwikpen confirmed by claims history or submission of medical records

**OR**

**1.1.2** History of contraindication or intolerance to insulin lispro Kwikpen (please specify intolerance or contraindication)

**AND**

**1.2** Prescriber provides a reason or special circumstance the patient has to use the Tempo product



|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                     |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Novolog Penfill, Novolog Flexpen, Fiasp Penfill, Fiasp Pumpcart, Fiasp FlexTouch                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                     |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | 12 month(s)         |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1 - One of the following:</b></p> <p><b>1.1 One of the following:</b></p> <p><b>1.1.1</b> Failure to insulin lispro vial confirmed by claims history or submission of medical records</p> <p style="text-align: center;"><b>OR</b></p> <p><b>1.1.2</b> History of contraindication or intolerance to insulin lispro vial (please specify intolerance or contraindication)</p> <p style="text-align: center;"><b>OR</b></p> <p><b>1.2 ONE of the following:</b></p> <ul style="list-style-type: none"> <li>• A visual impairment that prevents the patient from using a vial and syringe to accurately draw up the dose of insulin</li> <li>• A physical disability or handicap that prevents the patient from using a vial and syringe to draw up the dose and administer the insulin</li> <li>• The patient is unable to use the vial dosage form of the drug due to documented poor compliance with vials and syringes resulting in poorly controlled diabetes based on hemoglobin A1c</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>2 - One of the following:</b></p> <p><b>2.1</b> Failure to BOTH of the following confirmed by claims history or submission of medical records:</p> <ul style="list-style-type: none"> <li>• Insulin lispro Kwikpen</li> </ul> |                     |

- Insulin aspart pen or cartridge

**OR**

**2.2** History of contraindication or intolerance to BOTH of the following (please specify intolerance or contraindication):

- Insulin lispro Kwikpen
- Insulin aspart pen or cartridge

|                                                          |                     |
|----------------------------------------------------------|---------------------|
| Product Name:Novolin R Flexpen, Novolin R Flexpen Relion |                     |
| Approval Length                                          | 12 month(s)         |
| Guideline Type                                           | Prior Authorization |

**Approval Criteria**

**1 - ONE of the following:**

**1.1** Failure to ONE of the following confirmed by claims history or submission of medical records:

- Humulin R U-100 vial
- Novolin R U-100 vial

**OR**

**1.2** History of contraindication or intolerance to BOTH of the following (please specify intolerance or contraindication):

- Humulin R U-100 vial
- Novolin R U-100 vial

**OR**

**2 - ONE of the following:**

**2.1** A visual impairment that prevents the patient from using a vial and syringe to accurately draw up the dose of insulin

**OR**

**2.2** A physical disability or handicap that prevents the patient from using a vial and syringe to draw up the dose and administer the insulin

**OR**

**2.3** The patient is unable to use the vial dosage form of the drug due to documented poor compliance with vials and syringes resulting in poorly controlled diabetes based on hemoglobin A1c

Product Name:Humulin N Kwikpen, Novolin N Flexpen, Novolin N Flexpen Relion

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

### Approval Criteria

**1** - ONE of the following:

**1.1** Failure to ONE of the following confirmed by claims history or submission of medical records:

- Humulin N U-100 vial
- Novolin N U-100 vial

**OR**

**1.2** History of contraindication or intolerance to BOTH of the following (please specify intolerance or contraindication):

- Humulin N U-100 vial
- Novolin N U-100 vial

**OR**

**2 - ONE of the following:**

**2.1** A visual impairment that prevents the patient from using a vial and syringe to accurately draw up the dose of insulin

**OR**

**2.2** A physical disability or handicap that prevents the patient from using a vial and syringe to draw up the dose and administer the insulin

**OR**

**2.3** The patient is unable to use the vial dosage form of the drug due to documented poor compliance with vials and syringes resulting in poorly controlled diabetes based on hemoglobin A1c

Product Name:Humalog Mix Kwikpen 50/50, Insulin Aspart Flexpen 70/30, Humulin Kwikpen 70/30, Novolin Flexpen 70/30, Novolin Flexpen Relion 70/30

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

### Approval Criteria

**1 - ONE of the following:**

**1.1** Failure to the corresponding preferred insulin mix vial confirmed by claims history or submission of medical records

**OR**

**1.2** History of contraindication or intolerance to the corresponding preferred insulin mix vial (please specify intolerance or contraindication)

**OR**

**2 - ONE of the following:**

**2.1** A visual impairment that prevents the patient from using a vial and syringe to accurately draw up the dose of insulin

**OR**

**2.2** A physical disability or handicap that prevents the patient from using a vial and syringe to draw up the dose and administer the insulin

**OR**

**2.3** The patient is unable to use the vial dosage form of the drug due to documented poor compliance with vials and syringes resulting in poorly controlled diabetes based on hemoglobin A1c

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                     |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Novolog Mix 70/30 Flexpen, Novolog Mix 70/30 Flexpen Relion                                                                                                                                                                                                                                                                                                                                                                                         |                     |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 12 month(s)         |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1 - ONE of the following:</b></p> <p><b>1.1 ONE of the following:</b></p> <ul style="list-style-type: none"> <li>• Failure to the corresponding preferred insulin mix vial confirmed by claims history or submission of medical records</li> <li>• History of contraindication or intolerance to the corresponding preferred insulin mix vial (please specify intolerance or contraindication)</li> </ul> <p><b>OR</b></p> |                     |

**1.2 ONE of the following:**

- A visual impairment that prevents the patient from using a vial and syringe to accurately draw up the dose of insulin
- A physical disability or handicap that prevents the patient from using a vial and syringe to draw up the dose and administer the insulin
- The patient is unable to use the vial dosage form of the drug due to documented poor compliance with vials and syringes resulting in poorly controlled diabetes based on hemoglobin A1c

**AND**

**2 - ONE of the following:**

- Failure to Insulin Aspart Flexpen 70/30 100U/ML confirmed by claims history or submission of medical records
- History of contraindication or intolerance to Insulin Aspart Flexpen 70/30 100U/ML (please specify intolerance or contraindication)

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                     |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Humalog Mix Kwikpen 75/25                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                     |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 12 month(s)         |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1 - One of the following:</b></p> <p><b>1.1 ONE of the following:</b></p> <ul style="list-style-type: none"> <li>• Failure to the corresponding preferred insulin mix vial confirmed by claims history or submission of medical records</li> <li>• History of contraindication or intolerance to the corresponding preferred insulin mix vial (please specify intolerance or contraindication)</li> </ul> <p><b>OR</b></p> <p><b>1.2 ONE of the following:</b></p> |                     |

- A visual impairment that prevents the patient from using a vial and syringe to accurately draw up the dose of insulin
- A physical disability or handicap that prevents the patient from using a vial and syringe to draw up the dose and administer the insulin
- The patient is unable to use the vial dosage form of the drug due to documented poor compliance with vials and syringes resulting in poorly controlled diabetes based on hemoglobin A1c

**AND**

**2** - One of the following:

- Failure to insulin lispro protamine/insulin lispro Kwikpen 75/25 100U/ML confirmed by claims history or submission of medical records
- History of contraindication or intolerance to Insulin lispro protamine/insulin lispro Kwikpen 75/25 100U/ML (please specify intolerance or contraindication)

Product Name: Basaglar Kwikpen, Insulin Glargine Solostar 100U/ml, Insulin glargine-yfgn Pen, Semglee yfgn Pen Injector

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

### Approval Criteria

**1** - BOTH of the following:

**1.1** ONE of the following:

**1.1.1** Failure to BOTH of the following confirmed by claims history or submission of medical records:

- Rezvoglar Kwikpen
- Lantus (pens or vials)

**OR**

**1.1.2** History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- Rezvoglar Kwikpen
- Lantus (pens or vials)

**AND**

**1.2** The provider has given clinical justification why the patient is unable to use the preferred insulin glargine products

**Product Name:** Basaglar Tempo Pen

**Approval Length** 12 month(s)

**Guideline Type** Prior Authorization

**Approval Criteria**

**1** - BOTH of the following:

**1.1** ONE of the following:

**1.1.1** Failure to BOTH of the following confirmed by claims history or submission of medical records:

- Rezvoglar Kwikpen
- Lantus (pens or vials)

**OR**

**1.1.2** History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- Rezvoglar Kwikpen
- Lantus (pens or vials)

**AND**

**1.2** Prescriber provides a reason or special circumstance the patient has to use the Tempo product



|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                     |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Toujeo Solostar, Insulin Glargine Solostar 300U/ml, Toujeo Max Solostar, Insulin Glargine Max Solostar 300U/ml                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                     |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 12 month(s)         |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1 - BOTH of the following:</b></p> <p><b>1.1 ONE of the following:</b></p> <p><b>1.1.1</b> Failure to BOTH of the following confirmed by claims history or submission of medical records:</p> <ul style="list-style-type: none"> <li>• Rezvoglar Kwikpen</li> <li>• Lantus (pens or vials)</li> </ul> <p style="text-align: center;"><b>OR</b></p> <p><b>1.1.2</b> History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):</p> <ul style="list-style-type: none"> <li>• Rezvoglar Kwikpen</li> <li>• Lantus (pens or vials)</li> </ul> <p style="text-align: center;"><b>OR</b></p> <p><b>1.1.3</b> The provider has given clinical justification why the patient needs a concentrated glargine formulation</p> <p style="text-align: center;"><b>AND</b></p> <p><b>1.2</b> If the request is for Toujeo Solostar or Toujeo Solostar Max, ONE of the following:</p> <p><b>1.2.1</b> Failure to ONE of the following confirmed by claims history or submission of medical records:</p> <ul style="list-style-type: none"> <li>• Insulin glargine Solostar 300U/ml</li> </ul> |                     |

- Insulin glargine Max Solostar 300U/ml

**OR**

**1.2.2** History of intolerance or contraindication to ONE of the following (please specify intolerance or contraindication):

- Insulin glargine Solostar 300U/ml
- Insulin glargine Max Solostar 300U/ml

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                     |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Levemir Flexpen, Insulin Degludec Flextouch 100U/mL                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                     |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 12 month(s)         |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Failure to ONE of the following confirmed by claims history or submission of medical records:</p> <ul style="list-style-type: none"> <li>• Rezvoglar Kwikpen</li> <li>• Lantus (pens or vials)</li> </ul> <p><b>OR</b></p> <p><b>2</b> - History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):</p> <ul style="list-style-type: none"> <li>• Rezvoglar Kwikpen</li> <li>• Lantus (pens or vials)</li> </ul> |                     |

|                                        |                     |
|----------------------------------------|---------------------|
| Product Name:Tresiba Flextouch 100U/mL |                     |
| Approval Length                        | 12 month(s)         |
| Guideline Type                         | Prior Authorization |

**Approval Criteria**

**1** - One of the following:

**1.1** Failure to ONE of the following confirmed by claims history or submission of medical records:

- Rezvoglar Kwikpen
- Lantus (pens or vials)

**OR**

**1.2** History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- Rezvoglar Kwikpen
- Lantus (pens or vials)

**AND**

**2** - The provider has given clinical justification why the patient is unable to use the insulin degludec flextouch product

|                                                                                                                                                                                                                                                         |                     |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name: Insulin Degludec Flextouch 200U/mL                                                                                                                                                                                                        |                     |
| Approval Length                                                                                                                                                                                                                                         | 12 month(s)         |
| Guideline Type                                                                                                                                                                                                                                          | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Failure to ONE of the following confirmed by claims history or submission of medical records:</p> <ul style="list-style-type: none"> <li>• Rezvoglar Kwikpen</li> <li>• Lantus (pens or vials)</li> </ul> |                     |

**OR**

**2** - History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- Rezvoglar Kwikpen
- Lantus (pens or vials)

**OR**

**3** - The provider has given clinical justification why the patient needs a concentrated formulation

|                                        |                     |
|----------------------------------------|---------------------|
| Product Name:Tresiba Flextouch 200U/mL |                     |
| Approval Length                        | 12 month(s)         |
| Guideline Type                         | Prior Authorization |

**Approval Criteria**

**1** - One of the following:

**1.1** Failure to ONE of the following confirmed by claims history or submission of medical records:

- Rezvoglar Kwikpen
- Lantus (pens or vials)

**OR**

**1.2** History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- Rezvoglar Kwikpen
- Lantus (pens or vials)

**OR**

**1.3** The provider has given clinical justification why the patient needs a concentrated formulation

**AND**

**2** - The provider has given clinical justification why the patient is unable to use the insulin degludec flextouch product

**Product Name:**Insulin Glargine vial, Insulin glargine-yfgn vial, Semglee yfgn vial

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

### Approval Criteria

**1** - BOTH of the following:

**1.1** ONE of the following:

**1.1.1** Failure to BOTH of the following confirmed by claims history or submission of medical records:

- Rezvoglar Kwikpen
- Lantus (pens or vials)

**OR**

**1.1.2** History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- Rezvoglar Kwikpen
- Lantus (pens or vials)

**AND**

**1.2** The provider has given clinical justification why the patient is unable to use the preferred insulin glargine products

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                     |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Levemir vial, Insulin Degludec vial                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                     |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 12 month(s)         |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p>1 - ONE of the following:</p> <p>1.1 Failure to ONE of the following confirmed by claims history or submission of medical records:</p> <ul style="list-style-type: none"> <li>• Rezvoglar Kwikpen</li> <li>• Lantus (pens or vials)</li> </ul> <p style="text-align: center;"><b>OR</b></p> <p>1.2 History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):</p> <ul style="list-style-type: none"> <li>• Rezvoglar Kwikpen</li> <li>• Lantus (pens or vials)</li> </ul> |                     |

|                                                                                                                                                                                                                                                                                   |                     |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Tresiba vial                                                                                                                                                                                                                                                         |                     |
| Approval Length                                                                                                                                                                                                                                                                   | 12 month(s)         |
| Guideline Type                                                                                                                                                                                                                                                                    | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p>1 - One of the following:</p> <p>1.1 Failure to ONE of the following confirmed by claims history or submission of medical records:</p> <ul style="list-style-type: none"> <li>• Rezvoglar Kwikpen</li> <li>• Lantus (pens or vials)</li> </ul> |                     |

**OR**

**1.2** History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- Rezvoglar Kwikpen
- Lantus (pens or vials)

**AND**

**2** - The provider has given clinical justification why the patient is unable to use the insulin degludec product

Product Name:Admelog Solostar, Apidra, Insulin Aspart vial, Insulin Lispro vial, Humalog vial, Novolog vial, Novolog Relion vial, Fiasp vial, Lyumjev vial, Novolog Mix 70/30 vial, Novolog Mix 70/30 Relion vial, Humulin R U-500 vial, Apidra Solostar, Insulin Aspart Flexpen, Insulin Aspart Penfill, Insulin Lispro Junior Kwikpen, Insulin Lispro Kwikpen, Humalog Junior Kwikpen, Humalog Kwikpen, Humalog Tempo Pen, Novolog Flexpen, Novolog Flexpen Relion, Novolog Penfill, Fiasp Flextouch, Fiasp Penfill, Fiasp Pumpcart, Lyumjev Kwikpen, Lyumjev Tempo Pen, Novolin R Flexpen Relion, Novolin R Flexpen, Humulin R U-500 Kwikpen, Humulin N Kwikpen, Novolin N Flexpen Relion, Novolin N Flexpen, Humalog Mix 75/25 Kwikpen, Insulin Lispro Mix Kwikpen 75/25, Humalog Mix 50/50 Kwikpen, Insulin Aspart Protamine/Insulin Aspart 70/30 Flexpen, Humulin 70/30 Kwikpen, Novolin 70/30 Flexpen, Novolin 70/30 Flexpen Relion, Novolog Mix 70/30 Flexpen, Novolog Mix 70/30 Flexpen Relion, Lantus Solostar, Basaglar Tempo Pen, Toujeo Solostar, Insulin Glargine Solostar 300U/ml, Toujeo Max Solostar, Insulin Glargine Max Solostar 300U/ml, Semglee yfgn Pen Injector, Semglee yfgn vial, Levemir Flexpen, Tresiba Flextouch, Insulin Degludec Flextouch, Semglee vial, Lantus vial, Levemir vial, Tresiba vial, Insulin Degludec vial, Basaglar Kwikpen, Insulin Glargine vial, Insulin Glargine-YFGN pen and vial, Insulin Glargine Solostar 100U/ml, Humulin R vial, Novolin R vial, Novolin R Relion vial, Humulin N vial, Novolin N Relion vial, Novolin N vial, Insulin Aspart Protamine/Insulin Aspart 70/30 vial, Humalog Mix 75/25 vial, Humalog Mix 50/50 vial, Humulin 70/30 vial, Novolin 70/30 Relion vial, Novolin 70/30 vial, Admelog vial, Humalog Cartridge, Rezvoglar Kwikpen, Merilog vial, Merilog Solostar

|                 |                |
|-----------------|----------------|
| Approval Length | 12 month(s)    |
| Guideline Type  | Quantity Limit |

### Approval Criteria

**1** - Quantity requests exceeding the limited amount will be approved based on physician

confirmation that the patient requires a greater quantity due to poorly controlled diabetes based on blood glucose and/or hemoglobin A1c

## 2 . Background

### Benefit/Coverage/Program Information

#### Table 1. PDL Links

CO: <https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html>

HI: <https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html>

MD: <https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-cp-pharmacy.html>

NJ: <https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html>

NM: <https://www.uhcprovider.com/en/health-plans-by-state/new-mexico-health-plans/nm-comm-plan-home/nm-cp-pharmacy.html>

NY: <https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html>

PA: <https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP>

RI: <https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html>

## 3 . Revision History

| Date     | Notes         |
|----------|---------------|
| 9/3/2025 | Added Merilog |





Iqirvo



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-444203                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Guideline Name</b> | Iqirvo                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Washington (ACUWA, ACUWAAHE, ACUWAC)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 12/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                     |                       |
|---------------------|-----------------------|
| Product Name:Iqirvo |                       |
| Approval Length     | 12 month(s)           |
| Therapy Stage       | Initial Authorization |

| Guideline Type | Prior Authorization                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                | <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of primary biliary cholangitis</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Patient does not have decompensated cirrhosis</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - ONE of the following:</p> <p><b>3.1</b> BOTH of the following:</p> <p><b>3.1.1</b> Used in combination with ursodeoxycholic acid (e.g., Urso, ursodiol)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3.1.2</b> Patient has failed to achieve an alkaline phosphatase (ALP) level of less than 1.67 times the upper limit of normal after at least 12 consecutive months of treatment with ursodeoxycholic acid (e.g., Urso, ursodiol)</p> <p style="text-align: center;"><b>OR</b></p> <p><b>3.2</b> History of contraindication or intolerance to ursodeoxycholic acid (e.g., Urso, ursodiol)<br/>[please specify contraindication or intolerance]</p> <p style="text-align: center;"><b>AND</b></p> <p><b>4</b> - Patient is not receiving Iqirvo in combination with Livdelzi (seladelpar) or Ocaliva (obeticholic acid)</p> |

**AND**

**5** - Prescribed by ONE of the following:

- Hepatologist
- Gastroenterologist

Product Name: Iqirvo

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                 |
|---------------|-----------------|
| Therapy Stage | Reauthorization |
|---------------|-----------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

**1** - Submission of medical records (e.g., laboratory values) documenting a reduction in alkaline phosphatase (ALP) level from pre-treatment baseline (i.e., prior to Iqirvo therapy)

**AND**

**2** - Patient does not have decompensated cirrhosis

**AND**

**3** - Patient is not receiving Iqirvo in combination with Livdelzi (seladelpar) or Ocaliva (obeticholic acid)

**AND**

**4** - Prescribed by ONE of the following:

- Hepatologist
- Gastroenterologist

## 2 . Revision History

| Date      | Notes                                                                          |
|-----------|--------------------------------------------------------------------------------|
| 11/8/2025 | Combined formularies. No changes to clinical criteria. Minor cosmetic updates. |

Iressa



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-136146                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Guideline Name</b> | Iressa                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 1/1/2024 |
|-----------------|----------|

## 1 . Criteria

|                                               |                                    |
|-----------------------------------------------|------------------------------------|
| Product Name: Brand Iressa, generic gefitinib |                                    |
| Diagnosis                                     | Non-Small Cell Lung Cancer (NSCLC) |
| Approval Length                               | 12 month(s)                        |
| Therapy Stage                                 | Initial Authorization              |
| Guideline Type                                | Prior Authorization                |

**Approval Criteria**

1 - Diagnosis of metastatic non-small cell lung cancer (NSCLC)

**AND**

2 - ONE of the following:

2.1 Tumors are positive for epidermal growth factor receptor (EGFR) exon 19 deletions

**OR**

2.2 Tumors are positive for exon 21 (L858R) substitution mutations

**OR**

2.3 Tumors are positive for a known sensitizing EGFR mutation (e.g, exon 20 S7681 mutation, exon 18 G719X mutation, exon 21 L861Q mutation)

|                                                                                               |                                    |
|-----------------------------------------------------------------------------------------------|------------------------------------|
| Product Name:Brand Iressa, generic gefitinib                                                  |                                    |
| Diagnosis                                                                                     | Non-Small Cell Lung Cancer (NSCLC) |
| Approval Length                                                                               | 12 month(s)                        |
| Therapy Stage                                                                                 | Reauthorization                    |
| Guideline Type                                                                                | Prior Authorization                |
| <b>Approval Criteria</b><br>1 - Documentation of positive clinical response to Iressa therapy |                                    |

|                                              |                                      |
|----------------------------------------------|--------------------------------------|
| Product Name:Brand Iressa, generic gefitinib |                                      |
| Diagnosis                                    | Central Nervous System (CNS) Cancers |

|                                                                                                                                                                                                                                                                                                       |                       |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Approval Length                                                                                                                                                                                                                                                                                       | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                         | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                        | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of central nervous system (CNS) cancer with metastatic lesions</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Iressa is active against primary (NSCLC) tumor with a known epidermal growth factor receptor (EGFR) sensitizing mutation</p> |                       |

|                                                                                                                          |                                      |
|--------------------------------------------------------------------------------------------------------------------------|--------------------------------------|
| Product Name:Brand Iressa, generic gefitinib                                                                             |                                      |
| Diagnosis                                                                                                                | Central Nervous System (CNS) Cancers |
| Approval Length                                                                                                          | 12 month(s)                          |
| Therapy Stage                                                                                                            | Reauthorization                      |
| Guideline Type                                                                                                           | Prior Authorization                  |
| <p><b>Approval Criteria</b></p> <p>1 - Patient does not show evidence of progressive disease while on Iressa therapy</p> |                                      |

|                                              |                           |
|----------------------------------------------|---------------------------|
| Product Name:Brand Iressa, generic gefitinib |                           |
| Diagnosis                                    | NCCN Recommended Regimens |
| Approval Length                              | 12 month(s)               |
| Therapy Stage                                | Initial Authorization     |
| Guideline Type                               | Prior Authorization       |
| <p><b>Approval Criteria</b></p>              |                           |



**1** - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

|                                                                                                          |                           |
|----------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name: Brand Iressa, generic gefitinib                                                            |                           |
| Diagnosis                                                                                                | NCCN Recommended Regimens |
| Approval Length                                                                                          | 12 month(s)               |
| Therapy Stage                                                                                            | Reauthorization           |
| Guideline Type                                                                                           | Prior Authorization       |
| <b>Approval Criteria</b><br><br><b>1</b> - Documentation of positive clinical response to Iressa therapy |                           |

## 2 . Revision History

| Date       | Notes                                                                                                                            |
|------------|----------------------------------------------------------------------------------------------------------------------------------|
| 11/14/2023 | Updated list of examples of sensitizing EGFR mutations in NSCLC criteria, added generic gefitinib to GPI and product name lists. |

## Iron Chelators



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-369239                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Guideline Name</b> | Iron Chelators                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Michigan (ACUMI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 9/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                                                               |             |
|---------------------------------------------------------------|-------------|
| Product Name: Brand Exjade, Brand Jadenu, generic deferasirox |             |
| Approval Length                                               | 12 month(s) |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                       |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of chronic iron overload (e.g., sickle cell anemia, thalassemia, etc.) due to blood transfusion</p> <p style="text-align: center;"><b>OR</b></p> <p>2 - ALL of the following:</p> <ul style="list-style-type: none"> <li>• Diagnosis of chronic iron overload in non-transfusion dependent thalassemia (NTDT) syndrome</li> <li>• Patient has liver iron (Fe) concentration (LIC) levels consistently greater than or equal to 5 mg Fe per gram of dry weight prior to initiation of treatment with the requested medication</li> <li>• Patient has serum ferritin levels consistently greater than 300 micrograms per liter prior to initiation of treatment with the requested medication</li> </ul> |                       |

|                                                                                                                                                                                                                                                                                                                                                                   |                       |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name: Brand Ferriprox, generic deferiprone                                                                                                                                                                                                                                                                                                                |                       |
| Approval Length                                                                                                                                                                                                                                                                                                                                                   | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                     | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                    | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of transfusional iron overload due to thalassemia syndromes, sickle cell disease or other anemias</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Requested medication will NOT be used for the treatment of transfusional iron overload due to myelodysplastic syndrome or Diamond Blackfan anemia</p> |                       |

|                                                                                                     |                     |
|-----------------------------------------------------------------------------------------------------|---------------------|
| Product Name: Brand Exjade, Brand Jadenu, generic deferasirox, Brand Ferriprox, generic deferiprone |                     |
| Approval Length                                                                                     | 12 month(s)         |
| Therapy Stage                                                                                       | Reauthorization     |
| Guideline Type                                                                                      | Prior Authorization |
| <b>Approval Criteria</b><br><br>1 - Documentation of positive clinical response to therapy          |                     |

## 2 . Revision History

| Date      | Notes                                                            |
|-----------|------------------------------------------------------------------|
| 8/18/2025 | Updated formularies. Combined sections. Minor formatting updates |

Irritable Bowel Syndrome - Diarrhea



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-208216                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Guideline Name</b> | Irritable Bowel Syndrome - Diarrhea                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 4/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                                                |                       |
|------------------------------------------------|-----------------------|
| Product Name:generic alosetron, Brand Lotronex |                       |
| Approval Length                                | 12 month(s)           |
| Therapy Stage                                  | Initial Authorization |
| Guideline Type                                 | Prior Authorization   |

**Approval Criteria**

**1** - Diagnosis of severe diarrhea-predominant irritable bowel syndrome (IBS) with symptoms for at least six months

**AND**

**2** - Patient was female at birth

**AND**

**3** - ONE of the following:

**3.1** Failure to a tricyclic antidepressant (e.g., amitriptyline) as confirmed by claims history or submitted medical records

**OR**

**3.2** History of intolerance or contraindication to a tricyclic antidepressant (e.g., amitriptyline) (please specify intolerance or contraindication)

**AND**

**4** - Anatomic or biochemical abnormalities of the GI (gastrointestinal) tract have been excluded

|                                                |                     |
|------------------------------------------------|---------------------|
| Product Name:generic alosetron, Brand Lotronex |                     |
| Approval Length                                | 12 month(s)         |
| Therapy Stage                                  | Reauthorization     |
| Guideline Type                                 | Prior Authorization |
| <b>Approval Criteria</b>                       |                     |

1 - Documentation of positive clinical response to the requested therapy

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                       |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Viberzi                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                       |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of irritable bowel syndrome with diarrhea (IBS-D)</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - ONE of the following:</p> <p>    <b>2.1</b> Failure to a tricyclic antidepressant (e.g., amitriptyline) as confirmed by claims history or submitted medical records</p> <p style="text-align: center;"><b>OR</b></p> <p>    <b>2.2</b> History of intolerance or contraindication to a tricyclic antidepressant (e.g., amitriptyline) (please specify intolerance or contraindication)</p> |                       |

|                                                                                                           |                     |
|-----------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Viberzi                                                                                      |                     |
| Approval Length                                                                                           | 12 month(s)         |
| Therapy Stage                                                                                             | Reauthorization     |
| Guideline Type                                                                                            | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p>1 - Documentation of positive clinical response to Viberzi therapy</p> |                     |

## 2 . Revision History

| Date     | Notes               |
|----------|---------------------|
| 3/5/2025 | Updated formularies |



Isotretinoin



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-322214                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Guideline Name</b> | Isotretinoin                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 8/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                                                                                                          |                           |
|----------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name: Accutane, generic isotretinoin, Claravis, Amnesteem, Zenatane, Brand Absorica, Absorica LD |                           |
| Diagnosis                                                                                                | NCCN Recommended Regimens |
| Approval Length                                                                                          | 12 month(s)               |

|                                                                                                             |                       |
|-------------------------------------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                                               | Initial Authorization |
| Guideline Type                                                                                              | Prior Authorization   |
| <b>Approval Criteria</b><br><b>1</b> - Use is supported by The National Comprehensive Cancer Network (NCCN) |                       |

|                                                                                                          |                           |
|----------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name: Accutane, generic isotretinoin, Claravis, Amnesteem, Zenatane, Brand Absorica, Absorica LD |                           |
| Diagnosis                                                                                                | NCCN Recommended Regimens |
| Approval Length                                                                                          | 12 month(s)               |
| Therapy Stage                                                                                            | Reauthorization           |
| Guideline Type                                                                                           | Prior Authorization       |
| <b>Approval Criteria</b><br><b>1</b> - Documentation of positive clinical response to therapy            |                           |

|                                                                                                                                                                                                                                                      |                       |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name: Accutane, generic isotretinoin, Claravis, Amnesteem, Zenatane, Brand Absorica, Absorica LD                                                                                                                                             |                       |
| Diagnosis                                                                                                                                                                                                                                            | Acne                  |
| Approval Length                                                                                                                                                                                                                                      | 6 month(s)            |
| Therapy Stage                                                                                                                                                                                                                                        | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                       | Prior Authorization   |
| <b>Approval Criteria</b><br><b>1</b> - ONE of the following: <ul style="list-style-type: none"> <li>• Diagnosis of severe recalcitrant nodular acne unresponsive to conventional therapy</li> <li>• Diagnosis of treatment resistant acne</li> </ul> |                       |

**AND**

**2** - ONE of the following:

**2.1** Failure to an adequate trial on TWO of the following conventional therapy regimens confirmed by claims history or submission of medical records:

- Topical retinoid or retinoid-like agent [e.g., Retin-A/Retin-A Micro (tretinoin)]
- Oral antibiotic [e.g., Ery-Tab (erythromycin), Biaxin (clarithromycin), Minocin (minocycline)]
- Topical antibiotic with or without benzoyl peroxide [e.g., Cleocin-T (clindamycin), erythromycin, BenzaClin (benzoyl peroxide/clindamycin), Benzamycin (benzoyl peroxide/erythromycin)]

**OR**

**2.2** History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication):

- Topical retinoid or retinoid-like agent [e.g., Retin-A/Retin-A Micro (tretinoin)]
- Oral antibiotic [e.g., Ery-Tab (erythromycin), Biaxin (clarithromycin), Minocin (minocycline)]
- Topical antibiotic with or without benzoyl peroxide [e.g., Cleocin-T (clindamycin), erythromycin, BenzaClin (benzoyl peroxide/clindamycin), Benzamycin (benzoyl peroxide/erythromycin)]

**AND**

**3** - If the request is non-preferred\*, the prescriber has given a clinical reason or special circumstance why the patient is unable to use the preferred product (please document reason or special circumstance)

Notes

\*PDL links are listed in Background.

Product Name: Accutane, generic isotretinoin, Claravis, Amnesteem, Zenatane, Brand Absorica, Absorica LD

Diagnosis

Acne

Approval Length

6 month(s)

Therapy Stage

Reauthorization

Guideline Type

Prior Authorization

### Approval Criteria

**1** - After greater than or equal to 2 months OFF therapy, persistent or recurring severe recalcitrant nodular acne is still present

**OR**

**2** - Total cumulative dose for total duration of therapy is less than 150 mg/kg (document patient's dose and weight)\*

Notes

\*Will be approved up to a total of 150 mg/kg

## 2 . Background

### Benefit/Coverage/Program Information

#### PDL links

**CO:** <https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html>

**HI:** <https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html>

**MD:** <https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-cp-pharmacy.html>

**NJ:** <https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html>

**NY/NY EPP:** <https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html>

**PA CHIP:** <https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP>

**RI:** <https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html>

**VA:** <https://www.uhcprovider.com/en/health-plans-by-state/virginia-health-plans/va-comm-plan-home/va-cp-pharmacy.html>

**NE:** <https://www.uhcprovider.com/en/health-plans-by-state/nebraska-health-plans/ne-comm-plan-home/ne-cp-pharmacy.html>

**NM:** <https://www.uhcprovider.com/en/health-plans-by-state/new-mexico-health-plans/nm-comm-plan-home/nm-cp-pharmacy.html>

### 3 . Revision History

| Date     | Notes                                                                                                             |
|----------|-------------------------------------------------------------------------------------------------------------------|
| 7/9/2025 | Updated formularies and PDL links. Removed Myorisan. Updated NC CN language and added reauth. Updated NP language |

Isturisa



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-356207                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Guideline Name</b> | Isturisa                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Pennsylvania (ACUPA)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 9/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                 |             |
|-----------------|-------------|
| Product Name:   | Isturisa    |
| Approval Length | 12 month(s) |

|                                                                                                                                                                                                                                                                                                                   |                       |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                                                                                                                                                                                                                                                     | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                    | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of Cushing's syndrome</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - ONE of the following:</p> <ul style="list-style-type: none"> <li>• Patient is not a candidate for pituitary surgery</li> <li>• Pituitary surgery has not been curative</li> </ul> |                       |

|                                                                                                   |                     |
|---------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Isturisa                                                                             |                     |
| Approval Length                                                                                   | 12 month(s)         |
| Therapy Stage                                                                                     | Reauthorization     |
| Guideline Type                                                                                    | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p>1 - Documentation of positive response to Isturisa therapy</p> |                     |

## 2 . Revision History

| Date     | Notes                                                                                                                                       |
|----------|---------------------------------------------------------------------------------------------------------------------------------------------|
| 8/4/2025 | Combined formularies. Removed obsolete GPI for Isturisa 10mg strength. Updated verbiage in dx check criterion from "disease" to "syndrome". |

Itovebi



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-164670                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Guideline Name</b> | Itovebi                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 3/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                      |                       |
|----------------------|-----------------------|
| Product Name:Itovebi |                       |
| Diagnosis            | Breast Cancer         |
| Approval Length      | 12 month(s)           |
| Therapy Stage        | Initial Authorization |



| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Prior Authorization |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of breast cancer</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Disease is one of the following:</p> <ul style="list-style-type: none"> <li>• Locally advanced</li> <li>• Metastatic</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Disease is hormone receptor (HR)-positive</p> <p style="text-align: center;"><b>AND</b></p> <p><b>4</b> - Disease is human epidermal growth factor receptor 2 (HER2)-negative</p> <p style="text-align: center;"><b>AND</b></p> <p><b>5</b> - Disease is PIK3CA-mutation positive</p> <p style="text-align: center;"><b>AND</b></p> <p><b>6</b> - Used following recurrence on or after completing adjuvant endocrine therapy</p> <p style="text-align: center;"><b>AND</b></p> <p><b>7</b> - Used in combination with both of the following:</p> <ul style="list-style-type: none"> <li>• Ibrance (palbociclib)</li> </ul> |                     |

- Fulvestrant

|                                                                                                                       |                     |
|-----------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Itovebi                                                                                                  |                     |
| Diagnosis                                                                                                             | Breast Cancer       |
| Approval Length                                                                                                       | 12 month(s)         |
| Therapy Stage                                                                                                         | Reauthorization     |
| Guideline Type                                                                                                        | Prior Authorization |
| <b>Approval Criteria</b><br><b>1</b> - Patient does not show evidence of progressive disease while on Itovebi therapy |                     |

|                                                                                                                                            |                           |
|--------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Itovebi                                                                                                                       |                           |
| Diagnosis                                                                                                                                  | NCCN Recommended Regimens |
| Approval Length                                                                                                                            | 12 month(s)               |
| Therapy Stage                                                                                                                              | Initial Authorization     |
| Guideline Type                                                                                                                             | Prior Authorization       |
| <b>Approval Criteria</b><br><b>1</b> - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium |                           |

|                      |                           |
|----------------------|---------------------------|
| Product Name:Itovebi |                           |
| Diagnosis            | NCCN Recommended Regimens |
| Approval Length      | 12 month(s)               |
| Therapy Stage        | Reauthorization           |
| Guideline Type       | Prior Authorization       |
|                      |                           |

|                          |
|--------------------------|
| <b>Approval Criteria</b> |
|--------------------------|

|                                                                    |
|--------------------------------------------------------------------|
| 1 - Documentation of positive clinical response to Itovebi therapy |
|--------------------------------------------------------------------|

## 2 . Revision History

| Date     | Notes         |
|----------|---------------|
| 2/4/2025 | New guideline |

Iwifin



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-220213                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Guideline Name</b> | Iwifin                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Washington (ACUWA, ACUWAAHE, ACUWAC)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 5/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                     |                                |
|---------------------|--------------------------------|
| Product Name:Iwifin |                                |
| Diagnosis           | High-Risk Neuroblastoma (HRNB) |
| Approval Length     | 12 month(s)                    |

|                                                                                                                                                                                                                                                                                                                                                                                                           |                       |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                             | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                            | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of high-risk neuroblastoma (HRNB)</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Patient has shown at least a partial response to prior multiagent, multimodality therapy</p> <p style="text-align: center;"><b>AND</b></p> <p>3 - Prior therapy included anti-GD2 immunotherapy [e.g., Danyelza (naxitamab-gqqk), Unituxin (dinutuximab)]</p> |                       |

|                                                                                                                           |                                |
|---------------------------------------------------------------------------------------------------------------------------|--------------------------------|
| Product Name:lwilfin                                                                                                      |                                |
| Diagnosis                                                                                                                 | High-Risk Neuroblastoma (HRNB) |
| Approval Length                                                                                                           | 12 month(s)                    |
| Therapy Stage                                                                                                             | Reauthorization                |
| Guideline Type                                                                                                            | Prior Authorization            |
| <p><b>Approval Criteria</b></p> <p>1 - Patient does not show evidence of progressive disease while on lwilfin therapy</p> |                                |

|                      |                           |
|----------------------|---------------------------|
| Product Name:lwilfin |                           |
| Diagnosis            | NCCN Recommended Regimens |
| Approval Length      | 12 month(s)               |
| Therapy Stage        | Initial Authorization     |
| Guideline Type       | Prior Authorization       |

**Approval Criteria**

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

|                                                                                                          |                           |
|----------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name: Iwifin                                                                                     |                           |
| Diagnosis                                                                                                | NCCN Recommended Regimens |
| Approval Length                                                                                          | 12 month(s)               |
| Therapy Stage                                                                                            | Reauthorization           |
| Guideline Type                                                                                           | Prior Authorization       |
| <p><b>Approval Criteria</b></p> <p>1 - Documentation of positive clinical response to Iwifin therapy</p> |                           |

## 2 . Revision History

| Date      | Notes                                                                                                                                       |
|-----------|---------------------------------------------------------------------------------------------------------------------------------------------|
| 3/13/2025 | Combined formularies. Minor update to bracket punctuations in criterion 3 of HRNB initial auth section, with no changes to clinical intent. |

Jakafi



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-163749                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Guideline Name</b> | Jakafi                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 2/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                      |                       |
|----------------------|-----------------------|
| Product Name: Jakafi |                       |
| Diagnosis            | Myelofibrosis         |
| Approval Length      | 6 month(s)            |
| Therapy Stage        | Initial Authorization |
| Guideline Type       | Prior Authorization   |

**Approval Criteria**

**1** - ONE of the following diagnoses:

**1.1** Symptomatic lower-risk myelofibrosis

**OR**

**1.2** Intermediate or higher-risk myelofibrosis

**OR**

**1.3** Post-polycythemia vera myelofibrosis

**OR**

**1.4** Post-essential thrombocythemia myelofibrosis

**OR**

**1.5** Both of the following:

- Myelofibrosis-associated anemia
- Presence of symptomatic splenomegaly and/or constitutional symptoms

|                      |                       |
|----------------------|-----------------------|
| Product Name: Jakafi |                       |
| Diagnosis            | Polycythemia Vera     |
| Approval Length      | 6 month(s)            |
| Therapy Stage        | Initial Authorization |
| Guideline Type       | Prior Authorization   |



### Approval Criteria

**1** - Both of the following:

**1.1** Diagnosis of low-risk polycythemia vera

**AND**

**1.2** One of the following:

**1.2.1** Failure to ONE of the following as confirmed by claims history or submission of medical records:

- Hydroxyurea
- Interferon therapy (e.g., Intron A, Pegasys)

**OR**

**1.2.2** History of contraindication or intolerance to both of the following (please specify contraindication or intolerance):

- Hydroxyurea
- Interferon therapy (e.g., Intron A, Pegasys)

**OR**

**2** - Diagnosis of high-risk polycythemia vera

|                     |                           |
|---------------------|---------------------------|
| Product Name:Jakafi |                           |
| Diagnosis           | Essential Thrombocythemia |
| Approval Length     | 6 month(s)                |
| Therapy Stage       | Initial Authorization     |
| Guideline Type      | Prior Authorization       |

**Approval Criteria**

**1** - Diagnosis of essential thrombocythemia

**AND**

**2** - Inadequate response or loss of response to ONE of the following:

- Hydroxyurea
- Pegasys (peginterferon alfa-2a)
- Agrylin (Anagrelide)

**Product Name:**Jakafi

|           |                              |
|-----------|------------------------------|
| Diagnosis | Myeloproliferative Neoplasms |
|-----------|------------------------------|

|                 |            |
|-----------------|------------|
| Approval Length | 6 month(s) |
|-----------------|------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

**1** - Diagnosis of accelerated/blast phase myeloproliferative neoplasm

**AND**

**2** - Used for splenomegaly or other disease-related symptoms

**Product Name:**Jakafi

|           |                                                                                           |
|-----------|-------------------------------------------------------------------------------------------|
| Diagnosis | Myelofibrosis, Polycythemia Vera, Essential Thrombocythemia, Myeloproliferative Neoplasms |
|-----------|-------------------------------------------------------------------------------------------|

|                 |            |
|-----------------|------------|
| Approval Length | 6 month(s) |
|-----------------|------------|

|               |                 |
|---------------|-----------------|
| Therapy Stage | Reauthorization |
|---------------|-----------------|

|                                                                                                                                                          |                                                                                                                                                                                                                              |
|----------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Guideline Type                                                                                                                                           | Prior Authorization                                                                                                                                                                                                          |
| <b>Approval Criteria</b><br><br><b>1</b> - Documentation that patient has evidence of symptom improvement or reduction in spleen volume while on Jakafi* |                                                                                                                                                                                                                              |
| Notes                                                                                                                                                    | *If documentation does not provide evidence of symptom improvement or reduction in spleen volume while on Jakafi, authorization will be issued for 2 months to allow for dose titration with discontinuation of the therapy. |

|                                                                                                                                                                                                                                                                                                                                                                                               |                                  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|
| Product Name: Jakafi                                                                                                                                                                                                                                                                                                                                                                          |                                  |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                     | Graft versus host disease (GVHD) |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                               | 12 month(s)                      |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                 | Initial Authorization            |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                | Prior Authorization              |
| <b>Approval Criteria</b><br><br><b>1</b> - BOTH of the following:<br><br><b>1.1</b> Diagnosis of acute graft versus host disease (GVHD)<br><br><div style="text-align: center;"><b>AND</b></div><br><br><b>1.2</b> Disease is steroid refractory<br><br><div style="text-align: center;"><b>OR</b></div><br><br><b>2</b> - BOTH of the following:<br><br><b>2.1</b> Diagnosis of chronic GVHD |                                  |

**AND**

**2.2** Failure of one or two lines of systemic therapy

|                                                                                             |                                  |
|---------------------------------------------------------------------------------------------|----------------------------------|
| Product Name:Jakafi                                                                         |                                  |
| Diagnosis                                                                                   | Graft versus host disease (GVHD) |
| Approval Length                                                                             | 12 month(s)                      |
| Therapy Stage                                                                               | Reauthorization                  |
| Guideline Type                                                                              | Prior Authorization              |
| <b>Approval Criteria</b><br><b>1</b> - Documentation of symptom improvement while on Jakafi |                                  |

|                                                                                                                                                                                                                      |                            |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|
| Product Name:Jakafi                                                                                                                                                                                                  |                            |
| Diagnosis                                                                                                                                                                                                            | Myeloid/Lymphoid Neoplasms |
| Approval Length                                                                                                                                                                                                      | 12 month(s)                |
| Therapy Stage                                                                                                                                                                                                        | Initial Authorization      |
| Guideline Type                                                                                                                                                                                                       | Prior Authorization        |
| <b>Approval Criteria</b><br><b>1</b> - Diagnosis of lymphoid, myeloid, or mixed lineage neoplasms with eosinophilia<br><br><p style="text-align: center;"><b>AND</b></p> <b>2</b> - Patient has a JAK2 rearrangement |                            |

|                     |
|---------------------|
| Product Name:Jakafi |
|---------------------|

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Myelodysplastic Syndromes |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | 12 month(s)               |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Initial Authorization     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Prior Authorization       |
| <p><b>Approval Criteria</b></p> <p><b>1 - BOTH of the following:</b></p> <p><b>1.1</b> Diagnosis of chronic myelomonocytic leukemia (CMML)-2</p> <p style="text-align: center;"><b>AND</b></p> <p><b>1.2</b> Used in combination with a hypomethylating agent (e.g., azacitidine, decitabine)</p> <p style="text-align: center;"><b>OR</b></p> <p><b>2 - BOTH of the following:</b></p> <p><b>2.1</b> Diagnosis of myelodysplastic/myeloproliferative neoplasm (MDS/MPN) with neutrophilia</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2.2</b> Disease is positive for CSF3R or JAK2 mutation</p> |                           |

|                                 |                       |
|---------------------------------|-----------------------|
| Product Name: Jakafi            |                       |
| Diagnosis                       | T-Cell Lymphomas      |
| Approval Length                 | 12 month(s)           |
| Therapy Stage                   | Initial Authorization |
| Guideline Type                  | Prior Authorization   |
| <p><b>Approval Criteria</b></p> |                       |

**1 - Both of the following:**

**1.1** Diagnosis of one of the following:

- Peripheral T-cell lymphoma not otherwise specified (PTCL-NOS)
- Enteropathy-associated T-cell lymphoma (EATL)
- Monomorphic epitheliotropic intestinal T-cell lymphoma (MEITL)
- Angioimmunoblastic T-cell lymphoma (AITL)
- Nodal peripheral T-cell lymphoma with T-follicular helper phenotype (PTCL, TFH)
- Follicular T-cell lymphoma (FTCL)
- Anaplastic large cell lymphoma (ALCL)

**AND**

**1.2** Used as initial palliative intent therapy or second-line and subsequent therapy for relapsed/refractory disease

**OR**

**2 - Both of the following:**

**2.1** One of the following diagnoses:

- T-cell large granular lymphocytic leukemia
- T-cell prolymphocytic leukemia

**AND**

**2.2** Used as second-line or subsequent therapy

**OR**

**3 - Both of the following:**

**3.1** Diagnosis of hepatosplenic T-cell lymphoma

**AND**

**3.2** Used for refractory disease after two first-line therapy regimens

| Product Name:Jakafi                                                                                                      |                                                                         |
|--------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------|
| Diagnosis                                                                                                                | Myeloid/Lymphoid Neoplasms, Myelodysplastic Syndromes, T-Cell Lymphomas |
| Approval Length                                                                                                          | 12 month(s)                                                             |
| Therapy Stage                                                                                                            | Reauthorization                                                         |
| Guideline Type                                                                                                           | Prior Authorization                                                     |
| <p><b>Approval Criteria</b></p> <p>1 - Patient does not show evidence of progressive disease while on Jakafi therapy</p> |                                                                         |

| Product Name:Jakafi                                                                                                                                                                                  |                                        |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------|
| Diagnosis                                                                                                                                                                                            | Pediatric Acute Lymphoblastic Leukemia |
| Approval Length                                                                                                                                                                                      | 12 month(s)                            |
| Guideline Type                                                                                                                                                                                       | Prior Authorization                    |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of pediatric acute lymphoblastic leukemia</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Used as a component of consolidation therapy</p> |                                        |

| Product Name:Jakafi |                                  |
|---------------------|----------------------------------|
| Diagnosis           | Immunotherapy-Related Toxicities |
| Approval Length     | 12 month(s)                      |
| Guideline Type      | Prior Authorization              |

**Approval Criteria**

1 - Both of the following:

1.1 Diagnosis of CAR-T induced G4 cytokine release syndrome

**AND**

1.2 Disease is refractory to high-dose corticosteroids and anti-IL-6 therapy (e.g., Actemra [tocilizumab])

**OR**

2 - Both of the following:

2.1 Diagnosis of immune checkpoint inhibitor-related toxicities

**AND**

2.2 Used in combination with Orencia (abatacept) for the management of concomitant myositis and myocarditis

|                                                                                                                                                |                           |
|------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name: Jakafi                                                                                                                           |                           |
| Diagnosis                                                                                                                                      | NCCN Recommended Regimens |
| Approval Length                                                                                                                                | 12 month(s)               |
| Therapy Stage                                                                                                                                  | Initial Authorization     |
| Guideline Type                                                                                                                                 | Prior Authorization       |
| <p><b>Approval Criteria</b></p> <p>1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium</p> |                           |



|                                                                                                   |                           |
|---------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Jakafi                                                                               |                           |
| Diagnosis                                                                                         | NCCN Recommended Regimens |
| Approval Length                                                                                   | 12 month(s)               |
| Therapy Stage                                                                                     | Reauthorization           |
| Guideline Type                                                                                    | Prior Authorization       |
| <b>Approval Criteria</b><br><br>1 - Documentation of positive clinical response to Jakafi therapy |                           |

## 2 . Revision History

| Date      | Notes                                                                                                                    |
|-----------|--------------------------------------------------------------------------------------------------------------------------|
| 1/14/2025 | Multiple criteria updates, including new criteria for Myeloproliferative Neoplasms. Updated auth length for multiple dx. |

Jaypirca



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-219311                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Guideline Name</b> | Jaypirca                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 5/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                        |                       |
|------------------------|-----------------------|
| Product Name: Jaypirca |                       |
| Diagnosis              | B-Cell Lymphoma       |
| Approval Length        | 12 month(s)           |
| Therapy Stage          | Initial Authorization |

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Prior Authorization |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1 - Diagnosis of ONE of the following:</b></p> <ul style="list-style-type: none"> <li>• Extranodal marginal zone lymphoma of nongastric sites (noncutaneous)</li> <li>• Extranodal marginal zone lymphoma of the stomach</li> <li>• Mantle cell lymphoma (MCL)</li> <li>• Nodal marginal zone lymphoma</li> <li>• Splenic marginal zone lymphoma</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>2 - Disease is relapsed, refractory, or progressive</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>3 - Patient has received at least two prior systemic therapies [e.g., chemotherapy], one of which is a Bruton Tyrosine Kinase (BTK) inhibitor therapy [e.g., Imbruvica (ibrutinib), Calquence (acalabrutinib), Brukinsa (zanubrutinib)]</b></p> |                     |

|                                                                                                                                                                         |                                                         |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------|
| Product Name: Jaypirca                                                                                                                                                  |                                                         |
| Diagnosis                                                                                                                                                               | Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma |
| Approval Length                                                                                                                                                         | 12 month(s)                                             |
| Therapy Stage                                                                                                                                                           | Initial Authorization                                   |
| Guideline Type                                                                                                                                                          | Prior Authorization                                     |
| <p><b>Approval Criteria</b></p> <p><b>1 - Diagnosis of chronic lymphocytic leukemia or small lymphocytic lymphoma</b></p> <p style="text-align: center;"><b>AND</b></p> |                                                         |

**2** - Patient has been previously treated with BOTH of the following:

- Bruton Tyrosine Kinase (BTK) inhibitor therapy [e.g., Imbruvica (ibrutinib), Calquence (acalabrutinib), Brukinsa (zanubrutinib)]
- B-cell lymphoma 2 (BCL-2) inhibitor therapy [e.g., Venclexta (venetoclax)]

|                                                                                                                                                    |                                                          |
|----------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------|
| Product Name:Jaypirca                                                                                                                              |                                                          |
| Diagnosis                                                                                                                                          | Waldenström Macroglobulinemia/Lymphoplasmacytic Lymphoma |
| Approval Length                                                                                                                                    | 12 month(s)                                              |
| Therapy Stage                                                                                                                                      | Initial Authorization                                    |
| Guideline Type                                                                                                                                     | Prior Authorization                                      |
| <b>Approval Criteria</b><br><br><b>1</b> - Diagnosis of Waldenström Macroglobulinemia/Lymphoplasmacytic Lymphoma which has been previously treated |                                                          |

|                                                                                                                            |                                                                                                                                    |
|----------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------|
| Product Name:Jaypirca                                                                                                      |                                                                                                                                    |
| Diagnosis                                                                                                                  | B-Cell Lymphoma, Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma, Waldenström Macroglobulinemia/Lymphoplasmacytic Lymphoma |
| Approval Length                                                                                                            | 12 month(s)                                                                                                                        |
| Therapy Stage                                                                                                              | Reauthorization                                                                                                                    |
| Guideline Type                                                                                                             | Prior Authorization                                                                                                                |
| <b>Approval Criteria</b><br><br><b>1</b> - Patient does not show evidence of progressive disease while on Jaypirca therapy |                                                                                                                                    |

|                       |                           |
|-----------------------|---------------------------|
| Product Name:Jaypirca |                           |
| Diagnosis             | NCCN Recommended Regimens |
| Approval Length       | 12 month(s)               |

|                                                                                                                                                |                       |
|------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                                                                                  | Initial Authorization |
| Guideline Type                                                                                                                                 | Prior Authorization   |
| <b>Approval Criteria</b><br><br><b>1</b> - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium |                       |

|                                                                                                            |                           |
|------------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name: Jaypirca                                                                                     |                           |
| Diagnosis                                                                                                  | NCCN Recommended Regimens |
| Approval Length                                                                                            | 12 month(s)               |
| Therapy Stage                                                                                              | Reauthorization           |
| Guideline Type                                                                                             | Prior Authorization       |
| <b>Approval Criteria</b><br><br><b>1</b> - Documentation of positive clinical response to Jaypirca therapy |                           |

## 2 . Revision History

| Date      | Notes                                                                                                                                                 |
|-----------|-------------------------------------------------------------------------------------------------------------------------------------------------------|
| 3/24/2025 | Updated formularies. Added criteria for B-cell lymphomas and Waldenström Macroglobulinemia. Updated prior therapy language in B-cell lymphoma section |

Jesduvroq



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|-----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-228224                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Guideline Name</b> | Jesduvroq                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania (ACUPA)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Washington (ACUWA, ACUWAAHE, ACUWAC)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 5/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                        |                       |
|------------------------|-----------------------|
| Product Name:Jesduvroq |                       |
| Approval Length        | 12 month(s)           |
| Therapy Stage          | Initial Authorization |
| Guideline Type         | Prior Authorization   |

**Approval Criteria**

**1** - Diagnosis of anemia due to chronic kidney disease (CKD)

**AND**

**2** - Patient has been receiving dialysis for at least four months

**AND**

**3** - BOTH of the following:

- Ferritin greater than 100 mcg/L (micrograms per liter)
- Transferrin saturation (TSAT) greater than 20%

**AND**

**4** - Hemoglobin level is less than 11 g/dL (grams per deciliter)

**AND**

**5** - ONE of the following:

**5.1** Failure to an erythropoietin stimulating agent (ESA) [e.g., Aranesp (darbepoetin), Epogen (epoetin alfa), Procrit (epoetin alfa), Retacrit (epoetin alfa-epbx)] as confirmed by claims history or submission of medical records

**OR**

**5.2** History of contraindication or intolerance to an erythropoietin stimulating agent (ESA) (please specify contraindication or intolerance)

**AND**

**6** - Prescribed by or in consultation with ONE of the following:

- Hematologist
- Nephrologist

Product Name:Jesduvroq

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                 |
|---------------|-----------------|
| Therapy Stage | Reauthorization |
|---------------|-----------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

### Approval Criteria

**1** - Documentation of positive clinical response to Jesduvroq therapy (e.g., clinically meaningful increase in hemoglobin level)

**AND**

**2** - Adequate iron stores confirmed by both of the following:

- Ferritin greater than 100 mcg/L (micrograms per liter)
- Transferrin saturation (TSAT) greater than 20%

**AND**

**3** - Hemoglobin level does not exceed 12 g/dL (grams per deciliter)

**AND**

**4** - Patient is not on concurrent treatment with an erythropoietin stimulating agent (ESA) [e.g., Aranesp (darbepoetin), Epogen (epoetin alfa), Procrit (epoetin alfa), Retacrit (epoetin alfa-epbx)]

**AND**



**5** - Prescribed by or in consultation with ONE of the following:

- Hematologist
- Nephrologist

## **2 . Revision History**

| Date      | Notes               |
|-----------|---------------------|
| 3/27/2025 | Updated formularies |

Joenna



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-150140                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Guideline Name</b> | Joenna                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 8/1/2024 |
|-----------------|----------|

## 1 . Criteria

|                     |                       |
|---------------------|-----------------------|
| Product Name:Joenna |                       |
| Approval Length     | 12 month(s)           |
| Therapy Stage       | Initial Authorization |
| Guideline Type      | Prior Authorization   |
|                     |                       |

**Approval Criteria**

**1** - Diagnosis of activated phosphoinositide 3-kinase delta syndrome (APDS)

**AND**

**2** - Diagnosis has been confirmed by the presence of an APDS-associated genetic variant in either PIK3CD or PIK3R1

**AND**

**3** - Documentation of other clinical findings and manifestations consistent with APDS (e.g., recurrent respiratory tract infections, recurrent herpesvirus infections, lymphadenopathy, hepatosplenomegaly, autoimmune cytopenia)

**AND**

**4** - ONE of the following:

**4.1** Failure to one current standard of care for APDS (e.g., antimicrobial prophylaxis, immunoglobulin replacement therapy, immunosuppressive therapy) as confirmed by claims history or submission of medical records

**OR**

**4.2** History of contraindication or intolerance to one current standard of care for APDS (e.g., antimicrobial prophylaxis, immunoglobulin replacement therapy, immunosuppressive therapy) (please specify intolerance or contraindication)

**AND**

**5** - Prescribed by ONE of the following:

- Hematologist
- Immunologist

**AND**

**6 - BOTH of the following:**

- Patient is 12 years of age or older
- Patient weighs greater than or equal to 45 kg (kilograms)

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                     |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name: Joenja                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                     |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | 12 month(s)         |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1 - Documentation of positive clinical response to Joenja therapy (e.g., reduced lymph node size, increased naïve B-cell percentage, decreased frequency or severity of infections, decreased frequency of hospitalizations)</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>2 - Prescribed by ONE of the following:</b></p> <ul style="list-style-type: none"> <li>• Hematologist</li> <li>• Immunologist</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>3 - Patient weighs greater than or equal to 45 kg</b></p> |                     |

## 2 . Revision History

| Date      | Notes                                                |
|-----------|------------------------------------------------------|
| 7/23/2024 | Updated initial authorization duration to 12 months. |

Journavx



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-278309                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Guideline Name</b> | Journavx                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Michigan (ACUMI)</li> <li>• Medicaid - Community &amp; State Washington (ACUWA, ACUWAAHE, ACUWAC)</li> <li>• Medicaid - Community &amp; State Pennsylvania (ACUPA)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 7/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                        |                     |
|------------------------|---------------------|
| Product Name: Journavx |                     |
| Approval Length        | 14 Day(s)           |
| Guideline Type         | Prior Authorization |

### **Approval Criteria**

**1** - Diagnosis of moderate to severe acute pain

**AND**

**2** - Prescriber has given a clinical reason or special circumstance why the patient is unable to use an NSAID (nonsteroidal anti-inflammatory drug) (e.g., ibuprofen, naproxen) to treat the patient's pain (please document reason/special circumstance)

**AND**

**3** - Physician attests that Journavx will not be used for more than 14 days of therapy for the current pain episode

## **2 . Revision History**

| Date      | Notes                            |
|-----------|----------------------------------|
| 5/27/2025 | Updated formularies to remove VA |

Juxtapid



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-219320                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Guideline Name</b> | Juxtapid                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State Michigan (ACUMI)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 5/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                        |                       |
|------------------------|-----------------------|
| Product Name: Juxtapid |                       |
| Approval Length        | 12 month(s)           |
| Therapy Stage          | Initial Authorization |
| Guideline Type         | Prior Authorization   |

## **Approval Criteria**

**1** - Diagnosis of homozygous familial hypercholesterolemia (HoFH) as confirmed by ONE of the following:

**1.1** Submission of medical records (e.g., chart notes, laboratory values) confirming genetic confirmation of bi-allelic pathogenic/likely pathogenic variants on different chromosomes at the low-density lipoprotein receptor (LDLR), apolipoprotein B (APOB), proprotein convertase subtilisin kexin type 9 (PCSK9), or low-density lipoprotein receptor adaptor protein 1 (LDLRAP1) genes or greater than or equal to 2 such variants at different loci

**OR**

**1.2** BOTH of the following:

**1.2.1** Untreated low-density lipoprotein cholesterol (LDL-C) greater than 400 mg/dL

**AND**

**1.2.2** ONE of the following:

- Xanthoma before 10 years of age
- Evidence of familial hypercholesterolemia in at least one parent

**AND**

**2** - Patient is on a low-fat diet

**AND**

**3** - Patient is receiving other lipid-lowering therapy (e.g., statin, ezetimibe, LDL apheresis)

**AND**

**4** - Prescribed by ONE of the following:



- Cardiologist
- Endocrinologist
- Lipid specialist

**AND**

**5 - ONE of the following:**

**5.1** Failure to Repatha (evolocumab) as confirmed by claims history or submission of medical records

**OR**

**5.2** History of intolerance or contraindication to Repatha (evolocumab) (please specify intolerance or contraindication)

**AND**

**6 -** Not used in combination with a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor [e.g., Praluent (alirocumab), Repatha (evolocumab)]

**AND**

**7 -** Not used in combination with Evkeeza (evinacumab-dgnb)

|                                                                     |                     |
|---------------------------------------------------------------------|---------------------|
| Product Name:Juxtapid                                               |                     |
| Approval Length                                                     | 12 month(s)         |
| Therapy Stage                                                       | Reauthorization     |
| Guideline Type                                                      | Prior Authorization |
| <b>Approval Criteria</b><br><b>1 -</b> Patient is on a low-fat diet |                     |

**AND**

**2** - Patient continues to receive other lipid-lowering therapy (e.g., statin, low density lipoprotein [LDL] apheresis)

**AND**

**3** - Documentation of a positive clinical response to therapy from pre-treatment baseline

**AND**

**4** - Prescribed by ONE of the following:

- Cardiologist
- Endocrinologist
- Lipid specialist

**AND**

**5** - Not used in combination with a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor [e.g., Praluent (alirocumab), Repatha (evolocumab)]

**AND**

**6** - Not used in combination with Evkeeza (evinacumab-dgnb)

## 2 . Revision History

| Date      | Notes                                                                                                                                                                                                      |
|-----------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 3/20/2025 | Updated formularies. Updated diet requirement per label. Added requirement to not be used in combination with Evkeeza. Revised HoFH criteria to include more precise genetic terminology to account for ge |

|  |                                                                               |
|--|-------------------------------------------------------------------------------|
|  | netic test result interpretation complexity as well as digenic mutations<br>. |
|--|-------------------------------------------------------------------------------|

Kalydeco



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-353227                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Guideline Name</b> | Kalydeco                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 9/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                       |                       |
|-----------------------|-----------------------|
| Product Name:Kalydeco |                       |
| Approval Length       | 12 month(s)           |
| Therapy Stage         | Initial Authorization |
| Guideline Type        | Prior Authorization   |

**Approval Criteria**

**1** - Diagnosis of cystic fibrosis (CF)

**AND**

**2** - Submission of laboratory results confirming that patient has at least ONE of the mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to Kalydeco, listed in Table 1 (see Background)

**AND**

**3** - Prescribed by, or in consultation with a provider who specializes in the treatment of CF

|                                                                                                                                                                        |                     |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Kalydeco                                                                                                                                                  |                     |
| Approval Length                                                                                                                                                        | 12 month(s)         |
| Therapy Stage                                                                                                                                                          | Reauthorization     |
| Guideline Type                                                                                                                                                         | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of positive clinical response to Kalydeco therapy (e.g., improved lung function, stable lung function)</p> |                     |

## 2 . Background

|                                                                                                                                                    |
|----------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Benefit/Coverage/Program Information</b>                                                                                                        |
| <b>Table 1. CFTR Gene Mutations (A complete up to date list of responsive mutations can be referenced in the Kalydeco Prescribing Information)</b> |

|                |                |         |          |          |
|----------------|----------------|---------|----------|----------|
| 711+3A→G *     | F311del        | I148T   | R75Q     | S589N    |
| 2789+5G→A *    | F311L          | I175V   | R117C *  | S737F    |
| 3272-26A→G *   | F508C          | I807M   | R117G    | S945L *  |
| 3849+10kbC→T * | F508C;S1251N † | I1027T  | R117H *  | S977F *  |
| A120T          | F1052V         | I1139V  | R117L    | S1159F   |
| A234D          | F1074L         | K1060T  | R117P    | S1159P   |
| A349V          | G178E          | L206W * | R170H    | S1251N * |
| A455E *        | G178R *        | L320V   | R347H *  | S1255P * |
| A1067T         | G194R          | L967S   | R347L    | T338I    |
| D110E          | G314E          | L997F   | R352Q *  | T1053I   |
| D110H          | G551D *        | L1480P  | R553Q    | V232D    |
| D192G          | G551S *        | M152V   | R668C    | V562I    |
| D579G *        | G576A          | M952I   | R792G    | V754M    |
| D924N          | G970D          | M952T   | R933G    | V1293G   |
| D1152H *       | G1069R         | P67L *  | R1070Q   | W1282R   |
| D1270N         | G1244E *       | Q237E   | R1070W * | Y1014C   |
| E56K           | G1249R         | Q237H   | R1162L   | Y1032C   |

|         |          |        |         |  |
|---------|----------|--------|---------|--|
| E193K   | G1349D * | Q359R  | R1283M  |  |
| E822K   | H939R    | Q1291R | S549N * |  |
| E831X * | H1375P   | R74W   | S549R * |  |

\* Clinical data exist for these mutations.

† Complex/compound mutations where a single allele of the CFTR gene has multiple mutations; these exist independent of the presence of mutations on the other allele.

### 3 . Revision History

| Date     | Notes                                                           |
|----------|-----------------------------------------------------------------|
| 8/6/2025 | Added Virginia formulary. Updated background title information. |

Kerendia



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-433189                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Guideline Name</b> | Kerendia                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Pennsylvania (ACUPA)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 12/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                       |                              |
|-----------------------|------------------------------|
| Product Name:Kerendia |                              |
| Diagnosis             | Chronic kidney disease (CKD) |
| Approval Length       | 12 month(s)                  |



|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                       |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of chronic kidney disease (CKD) associated with type 2 diabetes (T2D)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - BOTH of the following:</p> <p><b>2.1</b> UACR (urinary albumin-to-creatinine ratio) greater than or equal to 30 mg/g</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2.2</b> eGFR (estimated glomerular filtration rate) greater than or equal to 25 mL/min/1.73 m<sup>2</sup></p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Kerendia is being used to reduce the risk of at least ONE of the following:</p> <ul style="list-style-type: none"> <li>• Sustained eGFR decline</li> <li>• End-stage kidney disease</li> <li>• Cardiovascular death</li> <li>• Non-fatal myocardial infarction</li> <li>• Hospitalization for heart failure</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>4</b> - Serum potassium level is less than or equal to 5 mEq/L (milliequivalents/liter) prior to initiating treatment</p> <p style="text-align: center;"><b>AND</b></p> <p><b>5</b> - ONE of the following:</p> |                       |

**5.1** Patient is on a stabilized dose and receiving concomitant therapy with ONE of the following as confirmed by claims history or submission of medical records:

- Maximally tolerated angiotensin converting enzyme (ACE) inhibitor (e.g., captopril, enalapril)
- Maximally tolerated angiotensin II receptor blocker (ARB) (e.g., candesartan, valsartan)

**OR**

**5.2** Patient has an allergy, contraindication, or intolerance to ACE inhibitors and ARBs (please specify allergy, contraindication, or intolerance)

**AND**

**6** - Prescriber attests the patient's diabetes is being managed with a diabetes medication with proven CKD benefit [e.g., SGLT2 inhibitor (e.g., Jardiance), GLP1 receptor agonist (e.g., Ozempic)]

|                                                                                                                                                                                                                               |                                                        |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------|
| Product Name:Kerendia                                                                                                                                                                                                         |                                                        |
| Diagnosis                                                                                                                                                                                                                     | Heart Failure with Preserved Ejection Fraction (HFpEF) |
| Approval Length                                                                                                                                                                                                               | 12 month(s)                                            |
| Therapy Stage                                                                                                                                                                                                                 | Initial Authorization                                  |
| Guideline Type                                                                                                                                                                                                                | Prior Authorization                                    |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of heart failure with preserved ejection fraction (HFpEF)</p> <p><b>AND</b></p> <p><b>2</b> - Ejection fraction is greater than or equal to 50%</p> <p><b>AND</b></p> |                                                        |

**3** - An eGFR of greater than or equal to 25 mL/min/1.73 m<sup>2</sup>

**AND**

**4** - Serum potassium level is less than or equal to 5 mEq/L prior to initiating treatment

**AND**

**5** - ONE of the following:

**5.1** Patient is on a stabilized dose and receiving concomitant therapy with ONE of the following as confirmed by claims history or submission of medical records:

- Maximally tolerated angiotensin converting enzyme (ACE) inhibitor (e.g., captopril, enalapril)
- Maximally tolerated angiotensin II receptor blocker (ARB) (e.g., candesartan, valsartan)
- Maximally tolerated angiotensin receptor-neprilysin inhibitor (ARNI) (e.g., sacubitril/valsartan)

**OR**

**5.2** Patient has an allergy, contraindication, or intolerance to ACE inhibitors, ARBs, and ARNIs (please specify allergy, contraindication, or intolerance)

**AND**

**6** - ONE of the following:

- Patient is on a stabilized dose and receiving concomitant therapy with a SGLT-2 inhibitor (e.g., Jardiance) as confirmed by claims history or submission of medical records
- Patient has an allergy, contraindication, or intolerance to a SGLT-2 inhibitor (e.g., Jardiance) (please specify allergy, contraindication, or intolerance)

**AND**

**7** - ONE of the following:

- History of trial and failure to a mineralocorticoid receptor antagonist [MRA (e.g., spironolactone, eplerenone)] as confirmed by claims history or submission of medical records
- Patient has an intolerance or contraindication to a mineralocorticoid receptor antagonist [MRA (e.g., spironolactone, eplerenone)] (please specify intolerance or contraindication)

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                              |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------|
| Product Name:Kerendia                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                              |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Heart Failure with mildly reduced ejection fraction (HFmrEF) |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | 12 month(s)                                                  |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Initial Authorization                                        |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Prior Authorization                                          |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of heart failure with mildly reduced ejection fraction (HFmrEF)</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Ejection fraction 40% to less than 50%</p> <p style="text-align: center;"><b>AND</b></p> <p>3 - An eGFR of greater than or equal to 25 mL/min/1.73 m<sup>2</sup></p> <p style="text-align: center;"><b>AND</b></p> <p>4 - Serum potassium level is less than or equal to 5 mEq/L prior to initiating treatment</p> <p style="text-align: center;"><b>AND</b></p> <p>5 - ONE of the following:</p> |                                                              |

**5.1** Patient is on a stabilized dose and receiving concomitant therapy with ONE of the following as confirmed by claims history or submission of medical records:

- Maximally tolerated angiotensin converting enzyme (ACE) inhibitor (e.g., captopril, enalapril)
- Maximally tolerated angiotensin II receptor blocker (ARB) (e.g., candesartan, valsartan)
- Maximally tolerated angiotensin receptor-neprilysin inhibitor (ARNI) (e.g., sacubitril/valsartan)

**OR**

**5.2** Patient has an allergy, contraindication, or intolerance to ACE inhibitors, ARBs, and ARNIs (please specify allergy, contraindication, or intolerance)

**AND**

**6** - ONE of the following:

- Patient is on a stabilized dose and receiving concomitant therapy with a SGLT-2 inhibitor (e.g., Jardiance) as confirmed by claims history or submission of medical records
- Patient has an allergy, contraindication, or intolerance to a SGLT-2 inhibitor (e.g., Jardiance) (please specify allergy, contraindication, or intolerance)

**AND**

**7** - ONE of the following:

- Patient is on a stabilized dose and receiving concomitant therapy with a beta-blocker (e.g., carvedilol, metoprolol succinate, bisoprolol) as confirmed by claims history or submission of medical records
- Patient has an allergy, contraindication, or intolerance to a beta-blocker (e.g., carvedilol, metoprolol succinate, bisoprolol) (please specify allergy, intolerance, or contraindication)

**AND**

**8** - ONE of the following:

- History of trial and failure to a mineralocorticoid receptor antagonist [MRA (e.g., spironolactone, eplerenone)] as confirmed by claims history or submission of medical records
- Patient has an intolerance or contraindication to a mineralocorticoid receptor antagonist [MRA (e.g., spironolactone, eplerenone)] (please specify intolerance or contraindication)

|                                                                                            |                     |
|--------------------------------------------------------------------------------------------|---------------------|
| Product Name:Kerendia                                                                      |                     |
| Diagnosis                                                                                  | CKD, HFpEF, HFmrEF  |
| Approval Length                                                                            | 12 month(s)         |
| Therapy Stage                                                                              | Reauthorization     |
| Guideline Type                                                                             | Prior Authorization |
| <b>Approval Criteria</b><br><br>1 - Documentation of positive clinical response to therapy |                     |

## 2 . Revision History

| Date       | Notes                                                                       |
|------------|-----------------------------------------------------------------------------|
| 10/27/2025 | Updated formularies to add PA-CAID for eff 12/1/25. Minor cosmetic updates. |

Keveyis, Ormalvi



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-238216                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Guideline Name</b> | Keveyis, Ormalvi                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania (ACUPA)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 5/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                                                                      |             |
|----------------------------------------------------------------------|-------------|
| Product Name: Brand Keveyis, generic dichlorphenamide, Brand Ormalvi |             |
| Approval Length                                                      | 12 month(s) |

|                                                                                                                                                                                                                                                   |                       |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                                                                                                                                                                                     | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                    | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of primary hyperkalemic periodic paralysis or related variant</p> <p style="text-align: center;"><b>OR</b></p> <p>2 - Diagnosis of primary hypokalemic periodic paralysis or related variant</p> |                       |

|                                                                                                                 |                     |
|-----------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name: Brand Keveyis, generic dichlorphenamide, Brand Ormalvi                                            |                     |
| Approval Length                                                                                                 | 12 month(s)         |
| Therapy Stage                                                                                                   | Reauthorization     |
| Guideline Type                                                                                                  | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p>1 - Documentation of positive clinical response to the requested therapy</p> |                     |

## 2 . Revision History

| Date      | Notes               |
|-----------|---------------------|
| 4/14/2025 | Updated formularies |



Kevzara



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-363192                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Guideline Name</b> | Kevzara                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 9/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                      |                       |
|----------------------|-----------------------|
| Product Name:Kevzara |                       |
| Diagnosis            | Rheumatoid Arthritis  |
| Approval Length      | 12 month(s)           |
| Therapy Stage        | Initial Authorization |
| Guideline Type       | Prior Authorization   |

### **Approval Criteria**

**1** - Diagnosis of moderately to severely active rheumatoid arthritis (RA)

**AND**

**2** - One of the following:

**2.1** Patient is currently on Kevzara therapy as confirmed by claims history or submission of medical records

**OR**

**2.2** All of the following:

**2.2.1** One of the following:

**2.2.1.1** Failure to a 3-month trial of one non-biologic disease modifying anti-rheumatic drug (DMARD) [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine] at maximally indicated doses as confirmed by claims history or submitted medical records

**OR**

**2.2.1.2** History of intolerance or contraindication to one non-biologic disease modifying anti-rheumatic drug (DMARD) [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine] (please specify intolerance or contraindication)

**OR**

**2.2.1.3** Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of rheumatoid arthritis as confirmed by claims history or submission of medical records [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab), Xeljanz/Xeljanz XR (tofacitinib)]

**AND**

**2.2.2** One of the following:

**2.2.2.1** Failure of one preferred adalimumab product\* confirmed by claims history or submitted medical records

**OR**

**2.2.2.2** History of intolerance or contraindication to all preferred adalimumab products\* (please specify intolerance or contraindication)

**AND**

**2.2.3** One of the following:

**2.2.3.1** Failure of Tyenne (tocilizumab-aazg) confirmed by claims history or submitted medical records

**OR**

**2.2.3.2** History of intolerance or contraindication to Tyenne (tocilizumab-aazg) (please specify intolerance or contraindication)

**AND**

**3** - Patient is not receiving Kevzara in combination with another targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab), Xeljanz/Xeljanz XR (tofacitinib)]

**AND**

**4** - Prescribed by or in consultation with a rheumatologist

Notes

\*See Table 1 for PDL Links

Product Name:Kevzara

Diagnosis

Rheumatoid Arthritis

|                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                     |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                       | 12 month(s)         |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                         | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                        | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of positive clinical response to Kevzara therapy</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Patient is not receiving Kevzara in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]</p> |                     |

|                                                                                                                                                                                                                                                                                                                                                                                                                     |                              |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|
| Product Name:Kevzara                                                                                                                                                                                                                                                                                                                                                                                                |                              |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                           | Polymyalgia Rheumatica (PMR) |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                     | 12 month(s)                  |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                       | Initial Authorization        |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                      | Prior Authorization          |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of polymyalgia rheumatica (PMR)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Patient has had an inadequate response to corticosteroids or cannot tolerate corticosteroid taper</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Patient is not receiving Kevzara in combination with another targeted immunomodulator</p> |                              |

[e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab), Xeljanz/Xeljanz XR (tofacitinib)]

| Product Name:Kevzara                                                                                                                                                                                                                                                                                                                                                                                                                               |                              |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                          | Polymyalgia Rheumatica (PMR) |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                    | 12 month(s)                  |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                      | Reauthorization              |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                     | Prior Authorization          |
| <p><b>Approval Criteria</b></p> <p>1 - Documentation of positive clinical response to Kevzara therapy</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Patient is not receiving Kevzara in combination with another targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab), Xeljanz/Xeljanz XR (tofacitinib)]</p> |                              |

| Product Name:Kevzara                                                                                                                                                                                                                                      |                                                    |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------|
| Diagnosis                                                                                                                                                                                                                                                 | Polyarticular Juvenile Idiopathic Arthritis (pJIA) |
| Approval Length                                                                                                                                                                                                                                           | 12 month(s)                                        |
| Therapy Stage                                                                                                                                                                                                                                             | Initial Authorization                              |
| Guideline Type                                                                                                                                                                                                                                            | Prior Authorization                                |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of active polyarticular juvenile idiopathic arthritis</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Patient is NOT receiving Kevzara in combination with another targeted immunomodulator</p> |                                                    |

[e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab), Xeljanz/Xeljanz XR (tofacitinib)]

**AND**

**3** - One of the following:

- Failure of one preferred adalimumab product\* confirmed by claims history or submitted medical records
- History of intolerance or contraindication to all preferred adalimumab products\* (please specify intolerance or contraindication)

**AND**

**4** - One of the following:

- Failure of Tyenne (tocilizumab-aazg) confirmed by claims history or submitted medical records
- History of intolerance or contraindication to Tyenne (tocilizumab-aazg) (please specify intolerance or contraindication)

**AND**

**5** - Prescribed by or in consultation with a rheumatologist

|       |                            |
|-------|----------------------------|
| Notes | *See Table 1 for PDL Links |
|-------|----------------------------|

|                                                                                                           |                                                    |
|-----------------------------------------------------------------------------------------------------------|----------------------------------------------------|
| Product Name:Kevzara                                                                                      |                                                    |
| Diagnosis                                                                                                 | Polyarticular Juvenile Idiopathic Arthritis (pJIA) |
| Approval Length                                                                                           | 12 month(s)                                        |
| Therapy Stage                                                                                             | Reauthorization                                    |
| Guideline Type                                                                                            | Prior Authorization                                |
| <b>Approval Criteria</b><br><br><b>1</b> - Documentation of positive clinical response to Kevzara therapy |                                                    |

**AND**

**2** - Patient is not receiving Kevzara in combination with another targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab), Xeljanz/Xeljanz XR (tofacitinib)]

## 2 . Background

### Benefit/Coverage/Program Information

#### Table 1: PDL Links

CO: <https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html>

HI: <https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html>

MD: <https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-cp-pharmacy.html>

NJ: <https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html>

NY/NY EPP: <https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html>

PA CHIP: <https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP>

RI: <https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html>

NM: <https://www.uhcprovider.com/en/health-plans-by-state/new-mexico-health-plans/nm-comm-plan-home/nm-cp-pharmacy.html>

### 3 . Revision History

| Date      | Notes                                                 |
|-----------|-------------------------------------------------------|
| 8/11/2025 | Updated language to targeted immunomodulator. Add NM. |



Kineret



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-160482                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Guideline Name</b> | Kineret                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 1/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                      |                           |
|----------------------|---------------------------|
| Product Name:Kineret |                           |
| Diagnosis            | Rheumatoid Arthritis (RA) |
| Approval Length      | 12 month(s)               |
| Therapy Stage        | Initial Authorization     |
| Guideline Type       | Prior Authorization       |
|                      |                           |

## **Approval Criteria**

**1** - Diagnosis of moderately to severely active rheumatoid arthritis (RA)

**AND**

**2** - Patient is NOT receiving Kineret in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

**AND**

**3** - Prescribed by or in consultation with a rheumatologist

**AND**

**4** - One of the following:

**4.1** Patient is currently on Kineret therapy as confirmed by claims history or submission of medical records

**OR**

**4.2** Both of the following:

**4.2.1** One of the following:

**4.2.1.1** Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of rheumatoid arthritis as confirmed by claims history or submission of medical records [e.g., Cimzia (certolizumab), adalimumab, Simponi (golimumab), Olumiant (baricitinib), Rinvoq (upadacitinib), Xeljanz (tofacitinib)]

**OR**

**4.2.1.2** Failure to a 3 month trial of one non-biologic DMARD [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine] at maximally indicated doses confirmed by claims history or submission of medical records

**OR**

**4.2.1.3** History of intolerance or contraindication to one non-biologic DMARD [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine] (please specify intolerance or contraindication)

**AND**

**4.2.2** One of the following:

**4.2.2.1** Failure of THREE of the following confirmed by claims history or submission of medical records:

- One of the preferred adalimumab products\*
- Enbrel (etanercept)
- Olumiant (baricitinib)
- Tyenne (tocilizumab-aazg)

**OR**

**4.2.2.2** History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication):

- One of the preferred adalimumab products\*
- Enbrel (etanercept)
- Olumiant (baricitinib)
- Tyenne (tocilizumab-aazg)

Notes

\* For a list of preferred adalimumab products please reference drug coverage tools.

|                      |                                                         |
|----------------------|---------------------------------------------------------|
| Product Name:Kineret |                                                         |
| Diagnosis            | Neonatal-Onset Multisystem Inflammatory Disease (NOMID) |
| Approval Length      | 12 month(s)                                             |
| Therapy Stage        | Initial Authorization                                   |
| Guideline Type       | Prior Authorization                                     |

### Approval Criteria

**1** - Diagnosis of neonatal-onset multisystem inflammatory disease (NOMID)

**AND**

**2** - Patient is NOT receiving Kineret in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

**AND**

**3** - Prescribed by or in consultation with a rheumatologist

| Product Name:Kineret                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                               |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                | Systemic Juvenile Idiopathic Arthritis (SJIA) |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                          | 12 month(s)                                   |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                            | Initial Authorization                         |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                           | Prior Authorization                           |
| <h3>Approval Criteria</h3> <p><b>1</b> - Diagnosis of active systemic juvenile idiopathic arthritis (SJIA) (formerly Still's Disease)</p> <p><b>AND</b></p> <p><b>2</b> - Patient is NOT receiving Kineret in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]</p> <p><b>AND</b></p> |                                               |

**3** - Prescribed by or in consultation with a rheumatologist

**AND**

**4** - One of the following:

**4.1** Patient is currently on Kineret therapy as confirmed by claims history or submission of medical records

**OR**

**4.2** One of the following:

**4.2.1** Failure of Tyenne (tocilizumab-aazg) confirmed by claims history or submitted medical records

**OR**

**4.2.2** History of intolerance or contraindication to Tyenne (tocilizumab-aazg) (please specify intolerance or contraindication)

|                                                                                                                                                                                                                      |                             |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|
| Product Name:Kineret                                                                                                                                                                                                 |                             |
| Diagnosis                                                                                                                                                                                                            | Adult Onset Still's Disease |
| Approval Length                                                                                                                                                                                                      | 12 month(s)                 |
| Therapy Stage                                                                                                                                                                                                        | Initial Authorization       |
| Guideline Type                                                                                                                                                                                                       | Prior Authorization         |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of adult onset Still's Disease</p> <p><b>AND</b></p> <p><b>2</b> - Patient is NOT receiving Kineret in combination with another targeted immunomodulator</p> |                             |

[e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

**AND**

**3** - Prescribed by or in consultation with a rheumatologist

| Product Name:Kineret                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                        |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------|
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Deficiency of Interleukin-1 Receptor Antagonist (DIRA) |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | 12 month(s)                                            |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Initial Authorization                                  |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Prior Authorization                                    |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of deficiency of Interleukin-1 Receptor Antagonist (DIRA)</p> <p><b>AND</b></p> <p><b>2</b> - Patient is NOT receiving Kineret in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]</p> <p><b>AND</b></p> <p><b>3</b> - Prescribed by or in consultation with a rheumatologist</p> |                                                        |

| Product Name:Kineret |                                                                                                                                                                                                                        |
|----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Diagnosis            | Rheumatoid Arthritis (RA), Neonatal-Onset Multisystem Inflammatory Disease (NOMID), Systemic Juvenile Idiopathic Arthritis (SJIA), Adult Onset Still's Disease, Deficiency of Interleukin-1 Receptor Antagonist (DIRA) |
| Approval Length      | 12 month(s)                                                                                                                                                                                                            |
| Therapy Stage        | Reauthorization                                                                                                                                                                                                        |

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                            | Prior Authorization |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of positive clinical response to Kineret therapy</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Patient is NOT receiving Kineret in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]</p> |                     |

## 2 . Revision History

| Date       | Notes                                          |
|------------|------------------------------------------------|
| 11/12/2024 | Removed Cimzia as an alternative in RA section |

Kisqali



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-354272                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Guideline Name</b> | Kisqali                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 9/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                      |                       |
|----------------------|-----------------------|
| Product Name:Kisqali |                       |
| Diagnosis            | Breast Cancer         |
| Approval Length      | 12 month(s)           |
| Therapy Stage        | Initial Authorization |



| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Prior Authorization |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1 - Diagnosis of ONE of the following:</b></p> <ul style="list-style-type: none"> <li>• Early stage (II or III) breast cancer at high-risk of recurrence</li> <li>• Advanced, recurrent, or metastatic breast cancer</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>2 - If for diagnosis of early stage (II or III) breast cancer at high-risk of recurrence, BOTH of the following:</b></p> <p><b>2.1 ONE of the following:</b></p> <ul style="list-style-type: none"> <li>• Disease is node-positive</li> <li>• Disease is node-negative with tumor size &gt; 5 cm</li> <li>• Disease is node-negative with tumor size 2-5 cm and Grade 2 and high genomic risk or Ki-67 at least 20%</li> <li>• Disease is node-negative with tumor size 2-5 cm and Grade 3</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>2.2 Used in combination with an aromatase inhibitor (e.g., anastrozole, letrozole, exemestane)</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>3 - If for diagnosis of advanced, recurrent, or metastatic breast cancer, ONE of the following:</b></p> <ul style="list-style-type: none"> <li>• Used in combination with an aromatase inhibitor (e.g., anastrozole, letrozole, exemestane)</li> <li>• Used in combination with Faslodex (fulvestrant)</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>4 - BOTH of the following:</b></p> |                     |

- Disease is hormone receptor (HR)-positive
- Disease is human epidermal growth factor receptor 2 (HER2)-negative

**AND**

**5 - ONE of the following:**

- Failure to Verzenio (abemaciclib) confirmed by claims history or submission of medical records
- History of contraindication or intolerance to Verzenio (abemaciclib) (please specify intolerance or contraindication)
- Patient is currently on Kisqali therapy

|                                                                                                                                                                                                                                                               |                       |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Kisqali                                                                                                                                                                                                                                          |                       |
| Diagnosis                                                                                                                                                                                                                                                     | Endometrial Carcinoma |
| Approval Length                                                                                                                                                                                                                                               | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                 | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1 - Diagnosis of recurrent or metastatic endometrial cancer</b></p> <p><b>AND</b></p> <p><b>2 - Tumor is estrogen receptor (ER)-positive</b></p> <p><b>AND</b></p> <p><b>3 - Used in combination with letrozole</b></p> |                       |

|                      |
|----------------------|
| Product Name:Kisqali |
|----------------------|

|                                                                                                                       |                                      |
|-----------------------------------------------------------------------------------------------------------------------|--------------------------------------|
| Diagnosis                                                                                                             | Breast Cancer, Endometrial Carcinoma |
| Approval Length                                                                                                       | 12 month(s)                          |
| Therapy Stage                                                                                                         | Reauthorization                      |
| Guideline Type                                                                                                        | Prior Authorization                  |
| <b>Approval Criteria</b><br><b>1</b> - Patient does not show evidence of progressive disease while on Kisqali therapy |                                      |

|                                                                                                                                            |                           |
|--------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Kisqali                                                                                                                       |                           |
| Diagnosis                                                                                                                                  | NCCN Recommended Regimens |
| Approval Length                                                                                                                            | 12 month(s)               |
| Therapy Stage                                                                                                                              | Initial Authorization     |
| Guideline Type                                                                                                                             | Prior Authorization       |
| <b>Approval Criteria</b><br><b>1</b> - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium |                           |

|                                                                                                       |                           |
|-------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Kisqali                                                                                  |                           |
| Diagnosis                                                                                             | NCCN Recommended Regimens |
| Approval Length                                                                                       | 12 month(s)               |
| Therapy Stage                                                                                         | Reauthorization           |
| Guideline Type                                                                                        | Prior Authorization       |
| <b>Approval Criteria</b><br><b>1</b> - Documentation of positive clinical response to Kisqali therapy |                           |

## 2 . Revision History

| Date     | Notes                          |
|----------|--------------------------------|
| 8/7/2025 | Updated breast cancer criteria |

Kisqali Femara Co-Pack



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-354273                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Guideline Name</b> | Kisqali Femara Co-Pack                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 9/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                                     |                       |
|-------------------------------------|-----------------------|
| Product Name:Kisqali Femara Co-Pack |                       |
| Diagnosis                           | Breast Cancer         |
| Approval Length                     | 12 month(s)           |
| Therapy Stage                       | Initial Authorization |

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Prior Authorization |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1 - Diagnosis of ONE of the following:</b></p> <ul style="list-style-type: none"> <li>• Early stage (II or III) breast cancer at high-risk of recurrence</li> <li>• Advanced, recurrent, or metastatic breast cancer</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>2 - If for diagnosis of early stage (II or III) breast cancer at high-risk of recurrence, ONE of the following:</b></p> <ul style="list-style-type: none"> <li>• Disease is node-positive</li> <li>• Disease is node-negative with tumor size &gt; 5 cm</li> <li>• Disease is node-negative with tumor size 2-5 cm and Grade 2 and high genomic risk or Ki-67 at least 20%</li> <li>• Disease is node-negative with tumor size 2-5 cm and Grade 3</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>3 - BOTH of the following:</b></p> <ul style="list-style-type: none"> <li>• Disease is hormone receptor (HR)-positive</li> <li>• Disease is human epidermal growth factor receptor 2 (HER2)-negative</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>4 - ONE of the following:</b></p> <ul style="list-style-type: none"> <li>• Failure to Verzenio (abemaciclib) plus an aromatase inhibitor (e.g., anastrozole, letrozole) confirmed by claims history or submission of medical records</li> <li>• History of contraindication or intolerance to Verzenio (abemaciclib) plus an aromatase inhibitor (e.g., anastrozole, letrozole) (please specify intolerance or contraindication)</li> <li>• Patient is currently on Kisqali Femara Co-Pack therapy</li> </ul> |                     |

Product Name:Kisqali Femara Co-Pack

|                                                                                                                                                                                                      |                       |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Diagnosis                                                                                                                                                                                            | Endometrial Carcinoma |
| Approval Length                                                                                                                                                                                      | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                        | Initial Authorization |
| Guideline Type                                                                                                                                                                                       | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of recurrent or metastatic endometrial cancer</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Tumor is estrogen receptor (ER)-positive</p> |                       |

|                                                                                                                                          |                                      |
|------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|
| Product Name:Kisqali Femara Co-Pack                                                                                                      |                                      |
| Diagnosis                                                                                                                                | Breast Cancer, Endometrial Carcinoma |
| Approval Length                                                                                                                          | 12 month(s)                          |
| Therapy Stage                                                                                                                            | Reauthorization                      |
| Guideline Type                                                                                                                           | Prior Authorization                  |
| <p><b>Approval Criteria</b></p> <p>1 - Patient does not show evidence of progressive disease while on Kisqali Femara Co-Pack therapy</p> |                                      |

|                                     |                           |
|-------------------------------------|---------------------------|
| Product Name:Kisqali Femara Co-Pack |                           |
| Diagnosis                           | NCCN Recommended Regimens |
| Approval Length                     | 12 month(s)               |
| Therapy Stage                       | Initial Authorization     |
| Guideline Type                      | Prior Authorization       |
|                                     |                           |

**Approval Criteria**

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Kisqali Femara Co-Pack

|           |                           |
|-----------|---------------------------|
| Diagnosis | NCCN Recommended Regimens |
|-----------|---------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                 |
|---------------|-----------------|
| Therapy Stage | Reauthorization |
|---------------|-----------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

1 - Documentation of positive clinical response to Kisqali Femara Co-Pack therapy

## 2 . Revision History

| Date | Notes |
|------|-------|
|------|-------|

|          |                                |
|----------|--------------------------------|
| 8/7/2025 | Updated breast cancer criteria |
|----------|--------------------------------|



Korlym



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|-----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-239240                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Guideline Name</b> | Korlym                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania (ACUPA)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Washington (ACUWA, ACUWAAHE, ACUWAC)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 6/1/2025 |
|-----------------|----------|

## 1 . Criteria

Product Name: Brand Korlym, generic mifepristone

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                       |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of endogenous Cushing's syndrome (i.e., hypercortisolism is not a result of chronic administration of high dose glucocorticoids)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - ONE of the following:</p> <ul style="list-style-type: none"> <li>• Diagnosis of type 2 diabetes mellitus</li> <li>• Diagnosis of glucose intolerance</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - ONE of the following:</p> <ul style="list-style-type: none"> <li>• Patient has failed surgery</li> <li>• Patient is not a candidate for surgery</li> </ul> |                       |

|                                                                                                                                |                     |
|--------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name: Brand Korlym, generic mifepristone                                                                               |                     |
| Approval Length                                                                                                                | 12 month(s)         |
| Therapy Stage                                                                                                                  | Reauthorization     |
| Guideline Type                                                                                                                 | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of a positive clinical response while on the requested therapy</p> |                     |

## 2 . Revision History

| Date      | Notes                                                  |
|-----------|--------------------------------------------------------|
| 4/15/2025 | Combined formularies. No changes to clinical criteria. |

Koselugo



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-448289                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Guideline Name</b> | Koselugo                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Washington (ACUWA, ACUWAAHE, ACUWAC)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 12/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                       |                          |
|-----------------------|--------------------------|
| Product Name:Koselugo |                          |
| Diagnosis             | Neurofibromatosis Type 1 |
| Approval Length       | 12 month(s)              |

|                                                                                                                                                                                                                                                                                                                                                                                                                                        |                       |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                          | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                         | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of neurofibromatosis type 1</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Patient has plexiform neurofibromas that are BOTH of the following:</p> <ul style="list-style-type: none"> <li>• Inoperable</li> <li>• Causing significant morbidity (e.g., disfigurement, motor dysfunction, pain, airway dysfunction, visual impairment, bladder/bowel dysfunction)</li> </ul> |                       |

|                                                                                                                                                                                                                                                                                            |                       |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Koselugo                                                                                                                                                                                                                                                                      |                       |
| Diagnosis                                                                                                                                                                                                                                                                                  | Glioma                |
| Approval Length                                                                                                                                                                                                                                                                            | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                              | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                             | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - ONE of the following:</p> <p>1.1 Circumscribed glioma with presence of BRAF fusion or BRAF V600E activating mutations</p> <p style="text-align: center;"><b>OR</b></p> <p>1.2 NF-1 mutated glioma</p> <p style="text-align: center;"><b>AND</b></p> |                       |

**2** - Disease is recurrent or progressive

**AND**

**3** - Used as monotherapy

Product Name:Koselugo

|           |                               |
|-----------|-------------------------------|
| Diagnosis | Langerhans Cell Histiocytosis |
|-----------|-------------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

### Approval Criteria

**1** - Diagnosis of Langerhans cell histiocytosis

**AND**

**2** - ONE of the following:

- Presence of mitogen-activated protein (MAP) kinase pathway mutation
- No detectable mutation
- Genetic testing not available

**AND**

**3** - Used as monotherapy

Product Name:Koselugo

|           |                                                                 |
|-----------|-----------------------------------------------------------------|
| Diagnosis | Neurofibromatosis Type 1, Glioma, Langerhans Cell Histiocytosis |
|-----------|-----------------------------------------------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                 |
|---------------|-----------------|
| Therapy Stage | Reauthorization |
|---------------|-----------------|

|                                                                                                                        |                     |
|------------------------------------------------------------------------------------------------------------------------|---------------------|
| Guideline Type                                                                                                         | Prior Authorization |
| <b>Approval Criteria</b><br><b>1</b> - Patient does not show evidence of progressive disease while on Koselugo therapy |                     |

|                                                                                                                                            |                           |
|--------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Koselugo                                                                                                                      |                           |
| Diagnosis                                                                                                                                  | NCCN Recommended Regimens |
| Approval Length                                                                                                                            | 12 month(s)               |
| Therapy Stage                                                                                                                              | Initial Authorization     |
| Guideline Type                                                                                                                             | Prior Authorization       |
| <b>Approval Criteria</b><br><b>1</b> - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium |                           |

|                                                                                                        |                           |
|--------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Koselugo                                                                                  |                           |
| Diagnosis                                                                                              | NCCN Recommended Regimens |
| Approval Length                                                                                        | 12 month(s)               |
| Therapy Stage                                                                                          | Reauthorization           |
| Guideline Type                                                                                         | Prior Authorization       |
| <b>Approval Criteria</b><br><b>1</b> - Documentation of positive clinical response to Koselugo therapy |                           |

## 2 . Revision History

|      |       |
|------|-------|
| Date | Notes |
|------|-------|

|            |                                                                                      |
|------------|--------------------------------------------------------------------------------------|
| 11/12/2025 | Combined formularies. No changes to clinical criteria. Expanded on MAP abbreviation. |
|------------|--------------------------------------------------------------------------------------|



Krazati



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-417192                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Guideline Name</b> | Krazati                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Washington (ACUWA, ACUWAAHE, ACUWAC)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 11/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                      |                                    |
|----------------------|------------------------------------|
| Product Name:Krazati |                                    |
| Diagnosis            | Non-Small Cell Lung Cancer (NSCLC) |
| Approval Length      | 12 month(s)                        |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                       |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of non-small cell lung cancer (NSCLC)</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Presence of KRAS G12C mutation</p> <p style="text-align: center;"><b>AND</b></p> <p>3 - Disease is ONE of the following:</p> <ul style="list-style-type: none"> <li>• Recurrent</li> <li>• Advanced</li> <li>• Metastatic</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p>4 - Patient has received at least one prior systemic therapy</p> |                       |

|                                                                           |                       |
|---------------------------------------------------------------------------|-----------------------|
| Product Name:Krazati                                                      |                       |
| Diagnosis                                                                 | Colorectal Cancer     |
| Approval Length                                                           | 12 month(s)           |
| Therapy Stage                                                             | Initial Authorization |
| Guideline Type                                                            | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of colorectal cancer</p> |                       |

|                                                                                                                                                     |
|-----------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>AND</b>                                                                                                                                          |
| <b>2</b> - Presence of KRAS G12C mutation                                                                                                           |
| <b>AND</b>                                                                                                                                          |
| <b>3</b> - Disease is ONE of the following: <ul style="list-style-type: none"> <li>• Recurrent</li> <li>• Advanced</li> <li>• Metastatic</li> </ul> |
| <b>AND</b>                                                                                                                                          |
| <b>4</b> - Patient has received at least one prior systemic therapy                                                                                 |

|                                                                                                                                                                                                                                                                        |                          |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|
| <b>Product Name:</b> Krazati                                                                                                                                                                                                                                           |                          |
| <b>Diagnosis</b>                                                                                                                                                                                                                                                       | Ampullary Adenocarcinoma |
| <b>Approval Length</b>                                                                                                                                                                                                                                                 | 12 month(s)              |
| <b>Therapy Stage</b>                                                                                                                                                                                                                                                   | Initial Authorization    |
| <b>Guideline Type</b>                                                                                                                                                                                                                                                  | Prior Authorization      |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of ampullary adenocarcinoma</p> <p style="text-align: center; padding: 20px 0;"><b>AND</b></p> <p><b>2</b> - Presence of KRAS G12C mutation</p> <p style="text-align: center; padding: 20px 0;"><b>AND</b></p> |                          |

**3** - Disease is ONE of the following:

- Recurrent
- Advanced
- Metastatic

**AND**

**4** - Patient has received at least one prior systemic therapy

|                      |                           |
|----------------------|---------------------------|
| Product Name:Krazati |                           |
| Diagnosis            | Pancreatic Adenocarcinoma |
| Approval Length      | 12 month(s)               |
| Therapy Stage        | Initial Authorization     |
| Guideline Type       | Prior Authorization       |

**Approval Criteria**

**1** - Diagnosis of pancreatic adenocarcinoma

**AND**

**2** - Presence of KRAS G12C mutation

**AND**

**3** - Disease is ONE of the following:

- Recurrent
- Advanced
- Metastatic

**AND**

**4** - Patient has received at least one prior systemic therapy

|                      |                       |
|----------------------|-----------------------|
| Product Name:Krazati |                       |
| Diagnosis            | Biliary Tract Cancers |
| Approval Length      | 12 month(s)           |
| Therapy Stage        | Initial Authorization |
| Guideline Type       | Prior Authorization   |

**Approval Criteria**

**1** - Diagnosis of ONE of the following:

- Gallbladder Cancer
- Intrahepatic cholangiocarcinoma
- Extrahepatic cholangiocarcinoma

**AND**

**2** - Presence of KRAS G12C mutation

**AND**

**3** - Disease is ONE of the following:

- Unresectable
- Resected gross residual (R2)
- Metastatic

**AND**

**4** - Patient has received at least one prior systemic therapy

|                      |
|----------------------|
| Product Name:Krazati |
|----------------------|

|                                                                                                                       |                                                                                                                                   |
|-----------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------|
| Diagnosis                                                                                                             | Non-Small Cell Lung Cancer (NSCLC), Colorectal Cancer, Ampullary Adenocarcinoma, Pancreatic Adenocarcinoma, Biliary Tract Cancers |
| Approval Length                                                                                                       | 12 month(s)                                                                                                                       |
| Therapy Stage                                                                                                         | Reauthorization                                                                                                                   |
| Guideline Type                                                                                                        | Prior Authorization                                                                                                               |
| <b>Approval Criteria</b><br><b>1</b> - Patient does not show evidence of progressive disease while on Krazati therapy |                                                                                                                                   |

|                                                                                                                                            |                           |
|--------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Krazati                                                                                                                       |                           |
| Diagnosis                                                                                                                                  | NCCN Recommended Regimens |
| Approval Length                                                                                                                            | 12 month(s)               |
| Therapy Stage                                                                                                                              | Initial Authorization     |
| Guideline Type                                                                                                                             | Prior Authorization       |
| <b>Approval Criteria</b><br><b>1</b> - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium |                           |

|                                                                                                       |                           |
|-------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Krazati                                                                                  |                           |
| Diagnosis                                                                                             | NCCN Recommended Regimens |
| Approval Length                                                                                       | 12 month(s)               |
| Therapy Stage                                                                                         | Reauthorization           |
| Guideline Type                                                                                        | Prior Authorization       |
| <b>Approval Criteria</b><br><b>1</b> - Documentation of positive clinical response to Krazati therapy |                           |

## 2 . Revision History

| Date      | Notes                                                  |
|-----------|--------------------------------------------------------|
| 10/9/2025 | Combined formularies. No changes to clinical criteria. |

Kuvan



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-451201                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Guideline Name</b> | Kuvan                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Pennsylvania (ACUPA)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 12/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                                               |                       |
|-----------------------------------------------|-----------------------|
| Product Name:generic sapropterin, Brand Kuvan |                       |
| Diagnosis                                     | Phenylketonuria (PKU) |
| Approval Length                               | 12 month(s)           |



|                                                                           |                     |
|---------------------------------------------------------------------------|---------------------|
| Guideline Type                                                            | Prior Authorization |
| <b>Approval Criteria</b><br><b>1 - Diagnosis of phenylketonuria (PKU)</b> |                     |

## 2 . Revision History

| Date       | Notes      |
|------------|------------|
| 11/11/2025 | Removed IN |

Lazcluze



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-160558                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Guideline Name</b> | Lazcluze                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 1/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                       |                                    |
|-----------------------|------------------------------------|
| Product Name:Lazcluze |                                    |
| Diagnosis             | Non-Small Cell Lung Cancer (NSCLC) |
| Approval Length       | 12 month(s)                        |
| Therapy Stage         | Initial Authorization              |
| Guideline Type        | Prior Authorization                |

**Approval Criteria**

1 - Diagnosis of non-small cell lung cancer (NSCLC)

**AND**

2 - Disease is ONE of the following:

- Recurrent
- Advanced
- Metastatic

**AND**

3 - Disease is positive for ONE of the following:

- Epidermal growth factor receptor (EGFR) exon 19 deletion
- EGFR exon 21 L858R mutation

**AND**

4 - Used in combination with Rybrevant (amivantamab-vmjw)

|                                                                                                                            |                                    |
|----------------------------------------------------------------------------------------------------------------------------|------------------------------------|
| Product Name:Lazcluze                                                                                                      |                                    |
| Diagnosis                                                                                                                  | Non-Small Cell Lung Cancer (NSCLC) |
| Approval Length                                                                                                            | 12 month(s)                        |
| Therapy Stage                                                                                                              | Reauthorization                    |
| Guideline Type                                                                                                             | Prior Authorization                |
| <p><b>Approval Criteria</b></p> <p>1 - Patient does not show evidence of progressive disease while on Lazcluze therapy</p> |                                    |

|                                                                                                                                         |                          |
|-----------------------------------------------------------------------------------------------------------------------------------------|--------------------------|
| Product Name:Lazcluze                                                                                                                   |                          |
| Diagnosis                                                                                                                               | NCCN Recommended Regimen |
| Approval Length                                                                                                                         | 12 month(s)              |
| Therapy Stage                                                                                                                           | Initial Authorization    |
| Guideline Type                                                                                                                          | Prior Authorization      |
| <b>Approval Criteria</b><br><br>1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium |                          |

|                                                                                                     |                          |
|-----------------------------------------------------------------------------------------------------|--------------------------|
| Product Name:Lazcluze                                                                               |                          |
| Diagnosis                                                                                           | NCCN Recommended Regimen |
| Approval Length                                                                                     | 12 month(s)              |
| Therapy Stage                                                                                       | Reauthorization          |
| Guideline Type                                                                                      | Prior Authorization      |
| <b>Approval Criteria</b><br><br>1 - Documentation of positive clinical response to Lazcluze therapy |                          |

## 2 . Revision History

| Date       | Notes       |
|------------|-------------|
| 11/13/2024 | New program |

Lenvima



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-222189                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Guideline Name</b> | Lenvima                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 5/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                      |                       |
|----------------------|-----------------------|
| Product Name:Lenvima |                       |
| Diagnosis            | Renal Cell Cancer     |
| Approval Length      | 12 month(s)           |
| Therapy Stage        | Initial Authorization |

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Prior Authorization |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1 - Diagnosis of advanced renal cell carcinoma</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>2 - ONE of the following:</b></p> <p><b>2.1 BOTH of the following:</b></p> <p><b>2.1.1 ONE of the following:</b></p> <ul style="list-style-type: none"> <li>• Failure to one prior anti-angiogenic therapy as confirmed by claims history or submission of medical records [e.g., Avastin (bevacizumab), Votrient (pazopanib), Sutent (sunitinib), Nexavar (sorafenib)]</li> <li>• History of intolerance or contraindication to one prior anti-angiogenic therapy [e.g., Avastin (bevacizumab), Votrient (pazopanib), Sutent (sunitinib), Nexavar (sorafenib)] (please specify contraindication or intolerance)</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>2.1.2 Used in combination with Afinitor (everolimus)</b></p> <p style="text-align: center;"><b>OR</b></p> <p><b>2.2 Used in combination with Keytruda (pembrolizumab)</b></p> |                     |

|                      |                     |
|----------------------|---------------------|
| Product Name:Lenvima |                     |
| Diagnosis            | Renal Cell Cancer   |
| Approval Length      | 12 month(s)         |
| Therapy Stage        | Reauthorization     |
| Guideline Type       | Prior Authorization |

**Approval Criteria**

**1** - Patient does not show evidence of progressive disease while on Lenvima therapy

**AND**

**2** - Used in combination with Afinitor (everolimus) or Keytruda (pembrolizumab)

Product Name:Lenvima

|           |                |
|-----------|----------------|
| Diagnosis | Thyroid Cancer |
|-----------|----------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

**1** - Diagnosis of differentiated thyroid cancer (DTC)

**AND**

**2** - Disease is locally recurrent, metastatic, progressive, or symptomatic

**AND**

**3** - Disease is radioactive iodine-refractory or ineligible

Product Name:Lenvima

|           |                       |
|-----------|-----------------------|
| Diagnosis | Hepatocellular Cancer |
|-----------|-----------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                                                                                                                                                                                        |                     |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Guideline Type                                                                                                                                                                         | Prior Authorization |
| <b>Approval Criteria</b><br><br><b>1</b> - Diagnosis of hepatocellular carcinoma<br><br><p style="text-align: center;"><b>AND</b></p> <b>2</b> - Disease is unresectable or metastatic |                     |

|                                                                               |                       |
|-------------------------------------------------------------------------------|-----------------------|
| Product Name:Lenvima                                                          |                       |
| Diagnosis                                                                     | Endometrial Carcinoma |
| Approval Length                                                               | 12 month(s)           |
| Therapy Stage                                                                 | Initial Authorization |
| Guideline Type                                                                | Prior Authorization   |
| <b>Approval Criteria</b><br><br><b>1</b> - Diagnosis of endometrial carcinoma |                       |

|                                                                                            |                          |
|--------------------------------------------------------------------------------------------|--------------------------|
| Product Name:Lenvima                                                                       |                          |
| Diagnosis                                                                                  | Adenoid Cystic Carcinoma |
| Approval Length                                                                            | 12 month(s)              |
| Therapy Stage                                                                              | Initial Authorization    |
| Guideline Type                                                                             | Prior Authorization      |
| <b>Approval Criteria</b><br><br><b>1</b> - Diagnosis of recurrent adenoid cystic carcinoma |                          |



|                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                       |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Lenvima                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                       |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Thymic Carcinoma      |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of thymic carcinoma</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - ONE of the following:</p> <ul style="list-style-type: none"> <li>Used as a single agent for those who cannot tolerate first-line combination regimens</li> <li>Used as a second line therapy in unresectable locally advanced disease, solitary metastasis or ipsilateral pleural metastasis, or extrathoracic metastatic disease</li> </ul> |                       |

|                                                                                                                           |                                                                                                          |
|---------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------|
| Product Name:Lenvima                                                                                                      |                                                                                                          |
| Diagnosis                                                                                                                 | Thyroid Cancer, Hepatocellular Cancer, Adenoid Cystic Carcinoma, Thymic Carcinoma, Endometrial Carcinoma |
| Approval Length                                                                                                           | 12 month(s)                                                                                              |
| Therapy Stage                                                                                                             | Reauthorization                                                                                          |
| Guideline Type                                                                                                            | Prior Authorization                                                                                      |
| <p><b>Approval Criteria</b></p> <p>1 - Patient does not show evidence of progressive disease while on Lenvima therapy</p> |                                                                                                          |

|                      |                    |
|----------------------|--------------------|
| Product Name:Lenvima |                    |
| Diagnosis            | Cutaneous Melanoma |
| Approval Length      | 12 month(s)        |

|                                                                                                                                                                                                                                                                                                                                                                                              |                       |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                               | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of cutaneous melanoma</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Disease is ONE of the following:</p> <ul style="list-style-type: none"> <li>• Disease is unresectable</li> <li>• Disease is metastatic</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p>3 - Used in combination with Keytruda (pembrolizumab)</p> |                       |

|                                                                                                                                                                                                                                      |                     |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Lenvima                                                                                                                                                                                                                 |                     |
| Diagnosis                                                                                                                                                                                                                            | Cutaneous Melanoma  |
| Approval Length                                                                                                                                                                                                                      | 12 month(s)         |
| Therapy Stage                                                                                                                                                                                                                        | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                       | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p>1 - Patient does not show evidence of progressive disease while on Lenvima therapy</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Used in combination with Keytruda (pembrolizumab)</p> |                     |

|                                                                                                                                                                    |                           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Lenvima                                                                                                                                               |                           |
| Diagnosis                                                                                                                                                          | NCCN Recommended Regimens |
| Approval Length                                                                                                                                                    | 12 month(s)               |
| Therapy Stage                                                                                                                                                      | Initial Authorization     |
| Guideline Type                                                                                                                                                     | Prior Authorization       |
| <b>Approval Criteria</b><br><br>1 - Lenvima will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium |                           |

|                                                                                                    |                           |
|----------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Lenvima                                                                               |                           |
| Diagnosis                                                                                          | NCCN Recommended Regimens |
| Approval Length                                                                                    | 12 month(s)               |
| Therapy Stage                                                                                      | Reauthorization           |
| Guideline Type                                                                                     | Prior Authorization       |
| <b>Approval Criteria</b><br><br>1 - Documentation of positive clinical response to Lenvima therapy |                           |

## 2 . Revision History

| Date      | Notes                                                                                                                  |
|-----------|------------------------------------------------------------------------------------------------------------------------|
| 3/24/2025 | Updated formularies. Removed criteria for biliary cancer. Removed combination use with Keytruda for endometrial cancer |

Leqembi IQLIK



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-435234                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Guideline Name</b> | Leqembi IQLIK                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania (ACUPA)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Michigan (ACUMI)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 12/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                            |                       |
|----------------------------|-----------------------|
| Product Name:Leqembi IQLIK |                       |
| Approval Length            | 12 month(s)           |
| Therapy Stage              | Initial Authorization |

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Prior Authorization |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1 - ONE of the following [Note: diagnoses based on National Institute on Aging and the Alzheimer's Association (NIA-AA) criteria]:</b></p> <p><b>1.1</b> Patient has mild cognitive impairment (MCI) due to Alzheimer's disease</p> <p style="text-align: center;"><b>OR</b></p> <p><b>1.2</b> Patient has mild dementia due to Alzheimer's disease</p> <p style="text-align: center;"><b>OR</b></p> <p><b>1.3</b> BOTH of the following:</p> <ul style="list-style-type: none"> <li>• Patient has progressed into moderate or severe stages of dementia due to Alzheimer's disease</li> <li>• Prescriber attests that the patient has shared in decision-making to continue Leqembi IQLIK therapy</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>2 -</b> Presence of amyloid beta pathology has been confirmed</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3 -</b> Patient has been established on intravenous Leqembi therapy under an active UnitedHealthcare medical benefit prior authorization</p> <p style="text-align: center;"><b>AND</b></p> <p><b>4 - BOTH of the following:</b></p> <p><b>4.1</b> Submission of medical records (e.g., chart notes) confirming follow-up brain magnetic</p> |                     |

resonance imaging (MRI) has been completed after the initiation of intravenous Leqembi therapy

**AND**

**4.2** ONE of the following:

**4.2.1** Amyloid-related imaging abnormalities (ARIA) have not been observed on MRI

**OR**

**4.2.2** ALL of the following:

**4.2.2.1** ARIA has been observed on MRI

**AND**

**4.2.2.2** Prescriber attests that continuation of therapy with Leqembi IQLIK is appropriate based on the severity of the patient's clinical symptoms

**AND**

**4.2.2.3** ONE of the following:

- Follow-up MRI demonstrates radiographic resolution and/or stabilization
- Prescriber attests that continuation of therapy with Leqembi IQLIK is appropriate based on the radiographic severity of ARIA

**AND**

**5** - Not used in combination with other A $\beta$  monoclonal antibodies (mAbs) for Alzheimer's Disease (e.g., Kisunla)

**AND**

**6** - Prescribed by a neurologist, geriatric psychiatrist, or geriatrician who specializes in treating dementia

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                     |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Leqembi IQLIK                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                     |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 12 month(s)         |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1 - ONE</b> of the following [Note: diagnoses based on National Institute on Aging and the Alzheimer's Association (NIA-AA) criteria]:</p> <p><b>1.1</b> Patient has mild cognitive impairment (MCI) due to Alzheimer's disease</p> <p style="text-align: center;"><b>OR</b></p> <p><b>1.2</b> Patient has mild dementia due to Alzheimer's disease</p> <p style="text-align: center;"><b>OR</b></p> <p><b>1.3 BOTH</b> of the following:</p> <ul style="list-style-type: none"> <li>• Patient has progressed into moderate or severe stages of dementia due to Alzheimer's disease</li> <li>• Prescriber attests that the patient has shared in decision-making to continue Leqembi IQLIK therapy</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>2 - Not</b> used in combination with other A<math>\beta</math> monoclonal antibodies (mAbs) for Alzheimer's Disease (e.g., Kisunla)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3 - Prescribed</b> by a neurologist, geriatric psychiatrist, or geriatrician who specializes in treating dementia</p> |                     |

## 2 . Revision History

| Date      | Notes        |
|-----------|--------------|
| 11/3/2025 | New Program. |



Leqselvi



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-435209                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Guideline Name</b> | Leqselvi                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 12/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                          |                       |
|--------------------------|-----------------------|
| Product Name:Leqselvi    |                       |
| Approval Length          | 12 month(s)           |
| Therapy Stage            | Initial Authorization |
| Guideline Type           | Prior Authorization   |
| <b>Approval Criteria</b> |                       |

**1** - Diagnosis of severe alopecia areata

**AND**

**2** - Other causes of hair loss have been ruled out (e.g., androgenetic alopecia, cicatricial alopecia, secondary syphilis, tinea capitis, triangular alopecia, and trichotillomania)

**AND**

**3** - Patient requesting therapy for current episode of alopecia areata

**AND**

**4** - ONE of the following:

- Failure to Olumiant confirmed by claims history or submission of medical records
- History of intolerance or contraindication to Olumiant (please specify intolerance or contraindication)

**AND**

**5** - Patient is not receiving Leqselvi in combination with any of the following:

- Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Rinvoq (upadacitinib), Litfulo (ritlecitinib), Olumiant (baricitinib)]
- Potent immunosuppressant (e.g., azathioprine or cyclosporine)

**AND**

**6** - Prescribed by or in consultation with a dermatologist

|                       |                 |
|-----------------------|-----------------|
| Product Name:Leqselvi |                 |
| Approval Length       | 12 month(s)     |
| Therapy Stage         | Reauthorization |

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Prior Authorization |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of positive clinical response to Leqselvi therapy</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Patient is not receiving Leqselvi in combination with any of the following:</p> <ul style="list-style-type: none"> <li>Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Rinvoq (upadacitinib), Litfulo (ritlecitinib), Olumiant (baricitinib)]</li> <li>Potent immunosuppressant (e.g., azathioprine or cyclosporine)</li> </ul> |                     |

## 2 . Revision History

| Date       | Notes                                                                                                                   |
|------------|-------------------------------------------------------------------------------------------------------------------------|
| 10/28/2025 | Removed criteria requiring a minimum of 50% scalp hair loss with current episode lasting six months under initial auth. |

Lidoderm



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|-----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-154785                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Guideline Name</b> | Lidoderm                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 10/1/2024 |
|-----------------|-----------|

## 1 . Criteria

|                                                         |                         |
|---------------------------------------------------------|-------------------------|
| Product Name:generic lidocaine 5% patch, Brand Lidoderm |                         |
| Diagnosis                                               | Post-Herpetic Neuralgia |
| Approval Length                                         | 12 month(s)             |
| Guideline Type                                          | Prior Authorization     |
| Approval Criteria                                       |                         |

**1 - Diagnosis of post-herpetic neuralgia**
**Product Name:**generic lidocaine 5% patch, Brand Lidoderm

|                 |                       |
|-----------------|-----------------------|
| Diagnosis       | Neuropathic Pain      |
| Approval Length | 12 month(s)           |
| Therapy Stage   | Initial Authorization |
| Guideline Type  | Prior Authorization   |

**Approval Criteria**
**1 - Diagnosis of neuropathic pain**

**AND**

**2 - ONE of the following:**
**2.1** Failure to ALL of the following as confirmed by claims history or submission of medical records:

- Tricyclic anti-depressant (e.g., amitriptyline)
- SNRI (serotonin and norepinephrine reuptake inhibitor) anti-depressant (e.g., duloxetine, venlafaxine)
- Anticonvulsant (e.g., gabapentin, pregabalin)

**OR**

**2.2** History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication):

- Tricyclic anti-depressant (e.g., amitriptyline)
- SNRI anti-depressant (e.g., duloxetine, venlafaxine)
- Anticonvulsant (e.g., gabapentin, pregabalin)

**Product Name:**generic lidocaine 5% patch, Brand Lidoderm

|           |                  |
|-----------|------------------|
| Diagnosis | Neuropathic Pain |
|-----------|------------------|

|                                                                                                          |                     |
|----------------------------------------------------------------------------------------------------------|---------------------|
| Approval Length                                                                                          | 12 month(s)         |
| Therapy Stage                                                                                            | Reauthorization     |
| Guideline Type                                                                                           | Prior Authorization |
| <b>Approval Criteria</b><br><br>1 - Documentation of positive clinical response to the requested therapy |                     |

## 2 . Revision History

| Date      | Notes                                                   |
|-----------|---------------------------------------------------------|
| 9/24/2024 | Updated formularies, updated GPI and product name lists |

Litfulo



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-433196                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Guideline Name</b> | Litfulo                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 12/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                      |                       |
|----------------------|-----------------------|
| Product Name:Litfulo |                       |
| Approval Length      | 12 month(s)           |
| Therapy Stage        | Initial Authorization |
| Guideline Type       | Prior Authorization   |
| Approval Criteria    |                       |

**1** - Diagnosis of severe alopecia areata

**AND**

**2** - Other causes of hair loss have been ruled out (e.g., androgenetic alopecia, cicatricial alopecia, secondary syphilis, tinea capitis, triangular alopecia, and trichotillomania)

**AND**

**3** - Patient requesting therapy for current episode of alopecia areata

**AND**

**4** - ONE of the following:

**4.1** Patient is less than 18 years of age

**OR**

**4.2** Failure to Olumiant confirmed by claims history or submission of medical records

**OR**

**4.3** History of intolerance or contraindication to Olumiant (please specify intolerance or contraindication)

**AND**

**5** - Patient is not receiving Litfulo in combination with either of the following:

- Targeted immunomodulator [e.g., Olumiant (baricitinib), Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Rinvoq (upadacitinib)]
- Potent immunosuppressant (e.g., azathioprine or cyclosporine)



**AND**

**6** - Prescribed by or in consultation with a dermatologist

Product Name:Litfulo

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                 |
|---------------|-----------------|
| Therapy Stage | Reauthorization |
|---------------|-----------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

### Approval Criteria

**1** - Documentation of positive clinical response to Litfulo therapy

**AND**

**2** - Patient is not receiving Litfulo in combination with either of the following:

- Targeted immunomodulator [e.g., Olumiant (baricitinib), Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Rinvoq (upadacitinib)]
- Potent immunosuppressant (e.g., azathioprine or cyclosporine)

## 2 . Revision History

| Date       | Notes                                                                             |
|------------|-----------------------------------------------------------------------------------|
| 10/27/2025 | Removed requirement for at least 50% scalp hair loss under initial auth criteria. |

Livdelzi



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-164659                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Guideline Name</b> | Livdelzi                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State Michigan (ACUMI)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Washington (ACUWA, ACUWAAHE, ACUWAC)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 3/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                 |             |
|-----------------|-------------|
| Product Name:   | Livdelzi    |
| Approval Length | 12 month(s) |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                       |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of primary biliary cholangitis</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Patient does not have decompensated cirrhosis</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - One of the following:</p> <p><b>3.1</b> Both of the following:</p> <ul style="list-style-type: none"> <li>• Used in combination with ursodeoxycholic acid (e.g., Urso, ursodiol)</li> <li>• Patient has failed to achieve an alkaline phosphatase (ALP) level of less than 1.67 times the upper limit of normal after at least 12 consecutive months of treatment with ursodeoxycholic acid (e.g., Urso, ursodiol)</li> </ul> <p style="text-align: center;"><b>OR</b></p> <p><b>3.2</b> History of contraindication or intolerance to ursodeoxycholic acid (e.g., Urso, ursodiol) (please specify contraindication or intolerance)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>4</b> - Patient is not receiving Livdelzi in combination with Iqirvo (elafibranor) or Ocaliva (obeticholic acid)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>5</b> - Prescribed by one of the following:</p> |                       |

- Hepatologist
- Gastroenterologist

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                     |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Livdelzi                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                     |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | 12 month(s)         |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Submission of medical records (e.g., laboratory values) documenting a reduction in alkaline phosphatase (ALP) level from pre-treatment baseline (i.e., prior to Livdelzi therapy)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Patient does not have decompensated cirrhosis</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Patient is not receiving Livdelzi in combination with Iqirvo (elafibranor) or Ocaliva (obeticholic acid)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>4</b> - Prescribed by one of the following:</p> <ul style="list-style-type: none"> <li>• Hepatologist</li> <li>• Gastroenterologist</li> </ul> |                     |

## 2 . Revision History

UnitedHealthcare Community Plan of New Jersey – Clinical Pharmacy Guidelines

| Date     | Notes       |
|----------|-------------|
| 2/4/2025 | New program |

Livmarli



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-435207                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Guideline Name</b> | Livmarli                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Pennsylvania (ACUPA)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 12/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                       |                                                      |
|-----------------------|------------------------------------------------------|
| Product Name:Livmarli |                                                      |
| Diagnosis             | Progressive Familial Intrahepatic Cholestasis (PFIC) |
| Approval Length       | 12 month(s)                                          |
| Therapy Stage         | Initial Authorization                                |
| Guideline Type        | Prior Authorization                                  |

### Approval Criteria

**1** - Diagnosis of progressive familial intrahepatic cholestasis (PFIC)

**AND**

**2** - Patient does not have a ABCB11 variant resulting in non-functional or complete absence of bile salt export pump (BSEP) protein

**AND**

**3** - Patient is experiencing cholestatic pruritus associated with PFIC

**AND**

**4** - Patient has a serum bile acid concentration above the upper limit of the normal reference range for the reporting laboratory

**AND**

**5** - Patient has had an inadequate response to at least two conventional treatments for the symptomatic relief of pruritus (e.g., ursodeoxycholic acid, diphenhydramine, cholestyramine, rifampin, naltrexone, and sertraline)

**AND**

**6** - Prescribed by a gastroenterologist or hepatologist

|                       |                                                      |
|-----------------------|------------------------------------------------------|
| Product Name:Livmarli |                                                      |
| Diagnosis             | Progressive Familial Intrahepatic Cholestasis (PFIC) |
| Approval Length       | 12 month(s)                                          |
| Therapy Stage         | Reauthorization                                      |

|                                                                                                                                                                                                                                                                                                                     |                     |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Guideline Type                                                                                                                                                                                                                                                                                                      | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of positive clinical response to Livmarli therapy (e.g., reduced serum bile acids, improved pruritus and less sleep disturbance)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Prescribed by a gastroenterologist or hepatologist</p> |                     |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                          |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|
| Product Name:Livmarli                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                          |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Alagille Syndrome (ALGS) |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 12 month(s)              |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Initial Authorization    |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Prior Authorization      |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of Alagille syndrome (ALGS)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Confirmation of diagnosis by presence of the JAG1 or Notch2 gene mutation</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Patient has a serum bile acid concentration above the upper limit of the normal reference range for the reporting laboratory</p> <p style="text-align: center;"><b>AND</b></p> |                          |



**4** - Patient is experiencing cholestatic pruritus associated with ALGS

**AND**

**5** - Patient has had an inadequate response to at least two conventional treatments for the symptomatic relief of pruritus (e.g., ursodeoxycholic acid, diphenhydramine, cholestyramine, rifampin, naltrexone, and sertraline)

**AND**

**6** - Prescribed by a gastroenterologist or hepatologist

|                                                                                                                                                                                                                                                              |                          |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|
| Product Name:Livmarli                                                                                                                                                                                                                                        |                          |
| Diagnosis                                                                                                                                                                                                                                                    | Alagille Syndrome (ALGS) |
| Approval Length                                                                                                                                                                                                                                              | 12 month(s)              |
| Therapy Stage                                                                                                                                                                                                                                                | Reauthorization          |
| Guideline Type                                                                                                                                                                                                                                               | Prior Authorization      |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of positive clinical response to Livmarli therapy (e.g., reduced serum bile acids, improved pruritus)</p> <p><b>AND</b></p> <p><b>2</b> - Prescribed by a gastroenterologist or hepatologist</p> |                          |

## 2 . Revision History

| Date | Notes |
|------|-------|
|------|-------|

|            |                                                                                                                                                                       |
|------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 10/28/2025 | Combined formularies. Removed the pruritus severity requirement and updated the type of pruritus under initial coverage criteria for PFIC and ALGS. Updated GPI list. |
|------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|

Livtency



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-230187                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Guideline Name</b> | Livtency                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Washington (ACUWA, ACUWAAHE, ACUWAC)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 5/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                 |            |
|-----------------|------------|
| Product Name:   | Livtency   |
| Approval Length | 2 month(s) |

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Prior Authorization |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of post-transplant cytomegalovirus (CMV) infection or CMV disease</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - CMV infection or disease is refractory to treatment (with or without genotypic resistance) to ONE of the following:</p> <ul style="list-style-type: none"> <li>• Ganciclovir</li> <li>• Valganciclovir</li> <li>• Cidofovir</li> <li>• Foscarnet</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Patient will not use Livtency in combination with ganciclovir or valganciclovir</p> |                     |

## 2 . Revision History

| Date      | Notes                 |
|-----------|-----------------------|
| 3/26/2025 | Combined formularies. |

Lokelma, Veltassa



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-448297                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Guideline Name</b> | Lokelma, Veltassa                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 12/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                                |                       |
|--------------------------------|-----------------------|
| Product Name:Lokelma, Veltassa |                       |
| Approval Length                | 12 month(s)           |
| Therapy Stage                  | Initial Authorization |
| Guideline Type                 | Prior Authorization   |

**Approval Criteria**

**1** - Diagnosis of non-life threatening hyperkalemia

**AND**

**2** - Where clinically appropriate, loop or thiazide diuretic therapy for potassium removal has failed

**AND**

**3** - Patient follows a low potassium diet (less than or equal to 3 grams per day)

|                                                                                                                                                                                                                                                                                                                                        |                     |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Lokelma, Veltassa                                                                                                                                                                                                                                                                                                         |                     |
| Approval Length                                                                                                                                                                                                                                                                                                                        | 12 month(s)         |
| Therapy Stage                                                                                                                                                                                                                                                                                                                          | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                                                                                                         | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Patient has a positive clinical response to Lokelma or Veltassa therapy</p> <p><b>AND</b></p> <p><b>2</b> - Patient continues to require treatment for hyperkalemia</p> <p><b>AND</b></p> <p><b>3</b> - Patient follows a low potassium diet (less than or equal to 3 grams per day)</p> |                     |

## 2 . Revision History

| Date       | Notes                                                                    |
|------------|--------------------------------------------------------------------------|
| 11/12/2025 | Combined formularies. Updated GPI list. No changes to clinical criteria. |

Long-Acting Opioid Products



## Prior Authorization Guideline

|                       |                                                                                                         |
|-----------------------|---------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-264203                                                                                               |
| <b>Guideline Name</b> | Long-Acting Opioid Products                                                                             |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>Medicaid - Community &amp; State New Jersey (PSI2300)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 7/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                  |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------|
| Product Name:generic morphine sulfate ER/CR tabs, fentanyl patches, hydrocodone bitartrate ER caps, oxymorphone ER, morphine sulfate ER caps, hydromorphone ER, generic hydrocodone bitartrate ER tabs, Brand Hysingla ER, Brand MS Contin, Nucynta ER, Oxycodone ER, Oxycontin, Xtampza ER, methadone 5 mg or 10 mg tabs/soln, generic methadone conc, Brand Methadose conc, tramadol ER, Conzip, Brand Zohydro ER |                                                                                                  |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                           | Opioid Naïve (Not having filled an opioid in the past 60 days) exceeding the 5 day supply limit* |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                      | DUR                                                                                              |
| <b>Approval Criteria</b><br><br>1 - ONE of the following:                                                                                                                                                                                                                                                                                                                                                           |                                                                                                  |



- Cancer-related pain (i.e., patients undergoing active cancer treatment; or cancer survivors with chronic pain who have completed cancer treatment, are in clinical remission, or are under cancer surveillance)
- End of life care, including hospice care
- Palliative care
- Sickle cell anemia

**OR**

**2** - Prescriber attests the patient has received an opioid within the past 60 days

|       |                                                                                                                                                                                                                   |
|-------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Notes | *Approval length for cancer-related pain, end of life, palliative care, or sickle cell pain will be issued for 12 months. All other approvals will be issued for the requested duration, not to exceed one month. |
|-------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

Product Name:generic morphine sulfate ER/CR tabs, fentanyl 12, 25, 50, 75, 100 mcg/hr patches

|                 |                                                             |
|-----------------|-------------------------------------------------------------|
| Diagnosis       | Cancer/Hospice/Sickle Cell Anemia/End of Life Related Pain* |
| Approval Length | 12 month(s)                                                 |
| Guideline Type  | Prior Authorization                                         |

### Approval Criteria

**1** - Patient is being treated for cancer-related pain (i.e., patients undergoing active cancer treatment; or cancer survivors with chronic pain who have completed cancer treatment, are in clinical remission, or are under cancer surveillance)

**OR**

**2** - Patient is in hospice or is receiving end of life care

**OR**

**3** - Patient is being treated for sickle cell anemia related pain

|       |                                                                                                                                                 |
|-------|-------------------------------------------------------------------------------------------------------------------------------------------------|
| Notes | *If the patient is currently taking the requested long-acting opioid for at least 30 days and does not meet the medical necessity authorization |
|-------|-------------------------------------------------------------------------------------------------------------------------------------------------|

|  |                                                                                                                                                                                                                                                                  |
|--|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | criteria requirements for treatment with an opioid, a denial should be issued and a maximum 60-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment. |
|--|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                             |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------|
| Product Name:hydrocodone bitartrate ER caps, methadone 5 mg or 10 mg tablets                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                             |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Cancer/Hospice/Sickle Cell Anemia/End of Life Related Pain* |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 12 month(s)                                                 |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Prior Authorization                                         |
| <p><b>Approval Criteria</b></p> <p><b>1 - ONE of the following:</b></p> <p><b>1.1</b> Patient is being treated for cancer-related pain (i.e., patients undergoing active cancer treatment; or cancer survivors with chronic pain who have completed cancer treatment, are in clinical remission, or are under cancer surveillance)</p> <p style="text-align: center;"><b>OR</b></p> <p><b>1.2</b> Patient is in hospice or is receiving end of life care</p> <p style="text-align: center;"><b>OR</b></p> <p><b>1.3</b> Patient is being treated for sickle cell anemia related pain</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2 - ONE of the following:</b></p> <p><b>2.1</b> The patient has failed a trial of at least ONE of the following, as confirmed by claims history or submission of medical records:</p> <ul style="list-style-type: none"> <li>• morphine sulfate controlled release tablets (generic MS Contin)</li> <li>• preferred fentanyl transdermal</li> </ul> |                                                             |

**OR**

**2.2** The patient has a history of contraindication or intolerance to BOTH of the following (please specify contraindication or intolerance):

- morphine sulfate controlled release tablets (generic MS Contin)
- preferred fentanyl transdermal

**OR**

**2.3** BOTH of the following:

**2.3.1** Patient is established on pain therapy with the requested medication for cancer-related pain (i.e., patients undergoing active cancer treatment; or cancer survivors with chronic pain who have completed cancer treatment, are in clinical remission, or are under cancer surveillance), hospice related pain, sickle cell anemia related pain, or end of life care related pain

**AND**

**2.3.2** The medication is not a new regimen for treatment of cancer-related pain (i.e., patients undergoing active cancer treatment; or cancer survivors with chronic pain who have completed cancer treatment, are in clinical remission, or are under cancer surveillance), hospice, sickle cell anemia related pain, or end of life care pain (document date regimen was started)

|       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|-------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Notes | <p>*If the patient is currently taking the requested long-acting opioid for at least 30 days and does not meet the medical necessity authorization criteria requirements for treatment with an opioid, a denial should be issued and a maximum 60-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment.</p> <p>If the request is for hydrocodone extended-release capsules (generic Zohydro ER), methadone 5 mg tablets or methadone 10 mg tablets and the patient is currently taking the requested long-acting opioid for at least 30 days and has met the medical necessity authorization criteria requirements for treatment with an opioid, but has not tried the preferred alternatives, a denial should be issued and a maximum 60-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment. Additionally, a 12 month authorization should be entered for morphine sulfate controlled release tablets (generic MS Contin) and preferred fentanyl transdermal.</p> |
|-------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                                                                                                                                                                                                                                                                                                                                |                                                             |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------|
| Product Name:morphine sulfate ER caps, hydromorphone ER, generic hydrocodone bitartrate ER tabs, Brand Hysingla ER, Brand MS Contin, Nucynta ER, Oxycodone ER, Oxycontin, oxymorphone ER, Xtampza ER, fentanyl 37.5, 62.5, 87.5 mcg/hr patches, methadone soln, generic methadone conc, Brand Methadose conc, Brand Zohydro ER |                                                             |
| Diagnosis                                                                                                                                                                                                                                                                                                                      | Cancer/Hospice/Sickle Cell Anemia/End of Life Related Pain* |
| Approval Length                                                                                                                                                                                                                                                                                                                | 12 month(s)                                                 |
| Guideline Type                                                                                                                                                                                                                                                                                                                 | Prior Authorization                                         |

**Approval Criteria**

**1 - ONE of the following:**

**1.1** Patient is being treated for cancer related pain (i.e., patients undergoing active cancer treatment; or cancer survivors with chronic pain who have completed cancer treatment, are in clinical remission, or are under cancer surveillance)

**OR**

**1.2** Patient is in hospice or is receiving end of life care

**OR**

**1.3** Patient is being treated for sickle cell anemia related pain

**AND**

**2 - ONE of the following:**

**2.1** The patient has failed a trial of ALL of the following, as confirmed by claims history or submission of medical records:

- morphine sulfate controlled release tablets (generic MS Contin)
- preferred fentanyl transdermal
- hydrocodone extended-release capsules (generic Zohydro ER)

**OR**

**2.2** The patient has a history of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):

- morphine sulfate controlled release tablets (generic MS Contin)
- preferred fentanyl transdermal
- hydrocodone extended-release capsules (generic Zohydro ER)

**OR**

**2.3** BOTH of the following:

**2.3.1** Patient is established on pain therapy with the requested medication for cancer-related pain (i.e., patients undergoing active cancer treatment; or cancer survivors with chronic pain who have completed cancer treatment, are in clinical remission, or are under cancer surveillance), hospice related pain, sickle cell anemia related pain, or end of life care related pain

**AND**

**2.3.2** The medication is not a new regimen for treatment of cancer-related pain (i.e., patients undergoing active cancer treatment; or cancer survivors with chronic pain who have completed cancer treatment, are in clinical remission, or are under cancer surveillance), hospice, sickle cell anemia related pain, or end of life care pain (Document date regimen was started)

|       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|-------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Notes | <p>*If the patient is currently taking the requested long-acting opioid for at least 30 days and does not meet the medical necessity authorization criteria requirements for treatment with an opioid, a denial should be issued and a maximum 60-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment.</p> <p>If the request is for a non-preferred product and the patient is currently taking the requested long-acting opioid for at least 30 days and has met the medical necessity authorization criteria requirements for treatment with an opioid, but has not tried the preferred alternatives, a denial should be issued and a maximum 60-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment. Additionally, a 12 month authorization should be entered for preferred products, depending on what the patient has already tried:</p> <ul style="list-style-type: none"> <li>• If the patient has tried morphine sulfate controlled release tablets (generic MS Contin) or preferred fentanyl transdermal, an authorization should be entered for hydrocodone extended-release capsules (generic Zohydro ER), methadone 5 mg tablets and methadone 10 mg tablets.</li> </ul> |
|-------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|--|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | <ul style="list-style-type: none"> <li>• If the patient has not tried any of the preferred products [morphine sulfate controlled release tablets (generic MS Contin), preferred fentanyl transdermal, hydrocodone extended-release capsules (generic Zohydro ER), methadone 5 mg tablets or methadone 10 mg tablets], an authorization should be entered for morphine sulfate controlled release tablets (generic MS Contin) and preferred fentanyl transdermal.</li> </ul> |
|--|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                  |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|
| Product Name:generic morphine sulfate ER/CR tabs, fentanyl 12, 25, 50, 75, 100 mcg/hr patches                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                  |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Non-cancer/Non-hospice/Non-sickle cell anemia/Non-end of life care related pain* |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 6 month(s)                                                                       |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Initial Authorization                                                            |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Prior Authorization                                                              |
| <p><b>Approval Criteria</b></p> <p><b>1 - Prescriber attests to BOTH of the following:</b></p> <p><b>1.1</b> Patient has been screened for substance abuse/opioid dependence</p> <p style="text-align: center;"><b>AND</b></p> <p><b>1.2</b> Pain is moderate to severe and expected to persist for an extended period of time (chronic)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2 - Treatment goals are defined and include estimated duration of treatment (must document treatment goals)</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>3 - BOTH of the following:</b></p> <p><b>3.1</b> Patient has been screened for underlying depression and/or anxiety</p> |                                                                                  |

**AND**

**3.2** If applicable, any underlying conditions have been or will be addressed

**AND**

**4** - ONE of the following:

**4.1** Prior to the start of therapy with the long-acting opioid, the patient has failed an adequate (minimum of 2 week) trial of a short-acting opioid within the last 30 days [document drug(s) and date of trial]

**OR**

**4.2** The patient is already receiving chronic opioid therapy prior to surgery for postoperative pain

**OR**

**4.3** Postoperative pain is expected to be moderate to severe and persist for an extended period of time

**OR**

**4.4** Patient is new to plan and currently established on long-acting opioid therapy for at least the past 30 days

**AND**

**5** - If the request is for neuropathic pain (examples of neuropathic pain include neuralgias and neuropathies), ONE of the following:

**5.1** BOTH of the following:

**5.1.1** Unless it is contraindicated, the patient has not exhibited an adequate response to 8

weeks of treatment with gabapentin titrated to a therapeutic dose (document date of trial) (if contraindicated, document contraindication)

**AND**

**5.1.2** Unless it is contraindicated, the patient has not exhibited an adequate response to at least 6 weeks of treatment with a tricyclic antidepressant titrated to the maximum tolerated dose (document drug and date of trial) (if contraindicated, document contraindication)

**OR**

**5.2** Patient is new to plan and currently established on long-acting opioid therapy for at least the past 30 days

|       |                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Notes | *If the patient is currently taking the requested long-acting opioid for at least 30 days and does not meet the medical necessity authorization criteria requirements for treatment with an opioid, a denial should be issued and a maximum 60-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment. |
|-------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

**Product Name:**hydrocodone bitartrate ER caps, methadone 5 mg or 10 mg tablets

|                 |                                                                                  |
|-----------------|----------------------------------------------------------------------------------|
| Diagnosis       | Non-cancer/Non-hospice/Non-sickle cell anemia/Non-end of life care related pain* |
| Approval Length | 6 month(s)                                                                       |
| Therapy Stage   | Initial Authorization                                                            |
| Guideline Type  | Prior Authorization                                                              |

### Approval Criteria

**1** - Prescriber attests to BOTH of the following:

**1.1** Patient has been screened for substance abuse/opioid dependence

**AND**



**1.2** Pain is moderate to severe and expected to persist for an extended period of time (chronic)

**AND**

**2** - Treatment goals are defined and include estimated duration of treatment (must document treatment goals)

**AND**

**3** - BOTH of the following:

**3.1** Patient has been screened for underlying depression and/or anxiety

**AND**

**3.2** If applicable, any underlying conditions have been or will be addressed

**AND**

**4** - ONE of the following:

**4.1** Prior to the start of therapy with the long-acting opioid, the patient has failed an adequate (minimum of 2 week) trial of a short-acting opioid within the last 30 days [document drug(s) and date of trial]

**OR**

**4.2** The patient is already receiving chronic opioid therapy prior to surgery for postoperative pain

**OR**

**4.3** Postoperative pain is expected to be moderate to severe and persist for an extended period of time

**OR**

**4.4** Patient is new to plan and currently established on long-acting opioid therapy for at least the past 30 days

**AND**

**5** - If the request is for neuropathic pain (examples of neuropathic pain include neuralgias and neuropathies), **ONE** of the following:

**5.1** BOTH of the following:

**5.1.1** Unless it is contraindicated, the patient has not exhibited an adequate response to 8 weeks of treatment with gabapentin titrated to a therapeutic dose (document date of trial) (if contraindicated, document contraindication)

**AND**

**5.1.2** Unless it is contraindicated, the patient has not exhibited an adequate response to at least 6 weeks of treatment with a tricyclic antidepressant titrated to the maximum tolerated dose (document drug and date of trial) (if contraindicated, document contraindication)

**OR**

**5.2** Patient is new to plan and currently established on long-acting opioid therapy for at least the past 30 days

**AND**

**6** - **ONE** of the following:

**6.1** Patient has failed a trial of at least **ONE** of the following, as confirmed by claims history or submission of medical records:

- morphine sulfate controlled release tablets (generic MS Contin)
- preferred fentanyl transdermal

**OR**

**6.2** Patient has a history of contraindication or intolerance to BOTH of the following (please specify contraindication or intolerance):

- morphine sulfate controlled release tablets (generic MS Contin)
- preferred fentanyl transdermal

|       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
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| Notes | <p>*If the patient is currently taking the requested long-acting opioid for at least 30 days and does not meet the medical necessity authorization criteria requirements for treatment with an opioid, a denial should be issued and a maximum 60-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment.</p> <p>If the request is for hydrocodone extended-release capsules (generic Zohydro ER), methadone 5 mg tablets or methadone 10 mg tablets and the patient is currently taking the requested long-acting opioid for at least 30 days and has met the medical necessity authorization criteria requirements for treatment with an opioid, but has not tried the preferred alternatives, a denial should be issued and a maximum 60-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment. Additionally, a 6 month authorization should be entered for morphine sulfate controlled release tablets (generic MS Contin) and preferred fentanyl transdermal.</p> |
|-------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                                                                                                                                                                                                                                                                                                                                |                                                                                  |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|
| Product Name:morphine sulfate ER caps, hydromorphone ER, generic hydrocodone bitartrate ER tabs, Brand Hysingla ER, Brand MS Contin, Nucynta ER, Oxycodone ER, Oxycontin, oxymorphone ER, Xtampza ER, fentanyl 37.5, 62.5, 87.5 mcg/hr patches, methadone soln, generic methadone conc, Brand Methadose conc, Brand Zohydro ER |                                                                                  |
| Diagnosis                                                                                                                                                                                                                                                                                                                      | Non-cancer/Non-hospice/Non-sickle cell anemia/Non-end of life care related pain* |
| Approval Length                                                                                                                                                                                                                                                                                                                | 6 month(s)                                                                       |
| Therapy Stage                                                                                                                                                                                                                                                                                                                  | Initial Authorization                                                            |
| Guideline Type                                                                                                                                                                                                                                                                                                                 | Prior Authorization                                                              |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Prescriber attests to BOTH of the following:</p> <p><b>1.1</b> Patient has been screened for substance abuse/opioid dependence</p>                                                                                                                                               |                                                                                  |

**AND**

**1.2** Pain is moderate to severe and expected to persist for an extended period of time (chronic)

**AND**

**2** - Treatment goals are defined and include estimated duration of treatment (must document treatment goals)

**AND**

**3** - BOTH of the following:

**3.1** Patient has been screened for underlying depression and/or anxiety

**AND**

**3.2** If applicable, any underlying conditions have been or will be addressed

**AND**

**4** - ONE of the following:

**4.1** Prior to the start of therapy with the long-acting opioid, the patient has failed an adequate (minimum of 2 week) trial of a short-acting opioid within the last 30 days [document drug(s) and date of trial]

**OR**

**4.2** The patient is already receiving chronic opioid therapy prior to surgery for postoperative pain

**OR**

**4.3** Postoperative pain is expected to be moderate to severe and persist for an extended period of time

**OR**

**4.4** Patient is new to plan and currently established on long-acting opioid therapy for at least the past 30 days

**AND**

**5** - If the request is for neuropathic pain (examples of neuropathic pain include neuralgias and neuropathies), **ONE** of the following:

**5.1** **BOTH** of the following:

**5.1.1** Unless it is contraindicated, the patient has not exhibited an adequate response to 8 weeks of treatment with gabapentin titrated to a therapeutic dose (document date of trial) (if contraindicated, document contraindication)

**AND**

**5.1.2** Unless it is contraindicated, the patient has not exhibited an adequate response to at least 6 weeks of treatment with a tricyclic antidepressant titrated to the maximum tolerated dose (document drug and date of trial) (if contraindicated, document contraindication)

**OR**

**5.2** Patient is new to plan and currently established on long-acting opioid therapy for at least the past 30 days

**AND**

**6** - **ONE** of the following:

**6.1** Patient has failed a trial of **ALL** of the following, as confirmed by claims history or submission of medical records:

- morphine sulfate controlled release tablets (generic MS Contin)

- preferred fentanyl transdermal
- hydrocodone extended-release capsules (generic Zohydro ER)

**OR**

**6.2** Patient has a history of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):

- morphine sulfate controlled release tablets (generic MS Contin)
- preferred fentanyl transdermal
- hydrocodone extended-release capsules (generic Zohydro ER)

|       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Notes | <p>*If the patient is currently taking the requested long-acting opioid for at least 30 days and does not meet the medical necessity authorization criteria requirements for treatment with an opioid, a denial should be issued and a maximum 60-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment.</p> <p>If the request is for a non-preferred product and the patient is currently taking the requested long-acting opioid for at least 30 days and has met the medical necessity authorization criteria requirements for treatment with an opioid, but has not tried the preferred alternatives, a denial should be issued and a maximum 60-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment. Additionally, a 6 month authorization should be entered for preferred products, depending on what the patient has already tried:</p> <ul style="list-style-type: none"> <li>• If the patient has tried morphine sulfate controlled release tablets (generic MS Contin) or preferred fentanyl transdermal, an authorization should be entered for hydrocodone extended-release capsules (generic Zohydro ER), methadone 5 mg tablets and methadone 10 mg tablets.</li> <li>• If the patient has not tried any of the preferred products [morphine sulfate controlled release tablets (generic MS Contin), preferred fentanyl transdermal, hydrocodone extended-release capsules (generic Zohydro ER), methadone 5 mg tablets or methadone 10 mg tablets], an authorization should be entered for morphine sulfate controlled release tablets (generic MS Contin) and preferred fentanyl transdermal.</li> </ul> |
|-------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                                                                                               |                                                                                  |
|-----------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|
| Product Name:generic morphine sulfate ER/CR tabs, fentanyl 12, 25, 50, 75, 100 mcg/hr patches |                                                                                  |
| Diagnosis                                                                                     | Non-cancer/Non-hospice/Non-sickle cell anemia/Non-end of life care related pain* |
| Approval Length                                                                               | 6 month(s)                                                                       |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                         |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Reauthorization                                                                                                                                                                                                                                                                                                                                                                                                         |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Prior Authorization                                                                                                                                                                                                                                                                                                                                                                                                     |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documented meaningful improvement in pain and function when assessed against treatment goals (document improvement in function or pain score improvement)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Document rationale for not tapering or discontinuing opioid if treatment goals are not being met</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Prescriber attests to BOTH of the following:</p> <p><b>3.1</b> Patient has been screened for substance abuse/opioid dependence</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3.2</b> Pain is moderate to severe and expected to persist for an extended period of time (chronic)</p> |                                                                                                                                                                                                                                                                                                                                                                                                                         |
| Notes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | <p>*If the patient is currently taking the requested long-acting opioid for at least 30 days and does not meet the medical necessity authorization criteria requirements for treatment with an opioid, a denial should be issued and a maximum 60-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment.</p> |

|                                                                              |                                                                                  |
|------------------------------------------------------------------------------|----------------------------------------------------------------------------------|
| Product Name:hydrocodone bitartrate ER caps, methadone 5 mg or 10 mg tablets |                                                                                  |
| Diagnosis                                                                    | Non-cancer/Non-hospice/Non-sickle cell anemia/Non-end of life care related pain* |
| Approval Length                                                              | 6 month(s)                                                                       |
| Therapy Stage                                                                | Reauthorization                                                                  |
| Guideline Type                                                               | Prior Authorization                                                              |

**Approval Criteria**

**1** - Documented meaningful improvement in pain and function when assessed against treatment goals (document improvement in function or pain score improvement)

**AND**

**2** - Document rationale for not tapering or discontinuing opioid if treatment goals are not being met

**AND**

**3** - Prescriber attests to BOTH of the following:

**3.1** Patient has been screened for substance abuse/opioid dependence

**AND**

**3.2** Pain is moderate to severe and expected to persist for an extended period of time (chronic)

**AND**

**4** - ONE of the following:

**4.1** Patient has failed a trial of at least ONE of the following, as confirmed by claims history or submission of medical records:

- morphine sulfate controlled release tablets (generic MS Contin)
- preferred fentanyl transdermal

**OR**

**4.2** Patient has a history of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):



|                                                                                                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"> <li>• morphine sulfate controlled release tablets (generic MS Contin)</li> <li>• preferred fentanyl transdermal</li> </ul> |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| Notes                                                                                                                                                         | <p>*If the patient is currently taking the requested long-acting opioid for at least 30 days and does not meet the medical necessity authorization criteria requirements for treatment with an opioid, a denial should be issued and a maximum 60-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment.</p> <p>If the request is for hydrocodone extended-release capsules (generic Zohydro ER), methadone 5 mg tablets or methadone 10 mg tablets and the patient is currently taking the requested long-acting opioid for at least 30 days and has met the medical necessity authorization criteria requirements for treatment with an opioid, but has not tried the preferred alternatives, a denial should be issued and a maximum 60-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment. Additionally, a 6 month authorization should be entered for morphine sulfate controlled release tablets (generic MS Contin) and preferred fentanyl transdermal.</p> |

|                                                                                                                                                                                                                                                                                                                                                                              |                                                                                  |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|
| Product Name:morphine sulfate ER caps, hydromorphone ER, generic hydrocodone bitartrate ER tabs, Brand Hysingla ER, Brand MS Contin, Nucynta ER, Oxycodone ER, Oxycontin, oxymorphone ER, Xtampza ER, fentanyl 37.5, 62.5, 87.5 mcg/hr patches, methadone soln, generic methadone conc, Brand Methadose conc, Brand Zohydro ER                                               |                                                                                  |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                    | Non-cancer/Non-hospice/Non-sickle cell anemia/Non-end of life care related pain* |
| Approval Length                                                                                                                                                                                                                                                                                                                                                              | 6 month(s)                                                                       |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                | Reauthorization                                                                  |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                               | Prior Authorization                                                              |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documented meaningful improvement in pain and function when assessed against treatment goals (document improvement in function or pain score improvement)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Document rationale for not tapering or discontinuing opioid if treatment goals are not being met</p> |                                                                                  |

**AND**

**3** - Prescriber attests to BOTH of the following:

**3.1** Patient has been screened for substance abuse/opioid dependence

**AND**

**3.2** Pain is moderate to severe and expected to persist for an extended period of time (chronic)

**AND**

**4** - ONE of the following:

**4.1** Patient has failed a trial of ALL the following, as confirmed by claims history or submission of medical records (document drugs and date of trials):

- morphine sulfate controlled release tablets (generic MS Contin)
- preferred fentanyl transdermal
- hydrocodone extended-release capsules (generic Zohydro ER)

**OR**

**4.2** Patient has a history of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):

- morphine sulfate controlled release tablets (generic MS Contin)
- preferred fentanyl transdermal
- hydrocodone extended-release capsules (generic Zohydro ER)

Notes

\*If the patient is currently taking the requested long-acting opioid for at least 30 days and does not meet the medical necessity authorization criteria requirements for treatment with an opioid, a denial should be issued and a maximum 60-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment.  
If the request is for a non-preferred product and the patient is currently taking the requested long-acting opioid for at least 30 days and has

|  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | <p>met the medical necessity authorization criteria requirements for treatment with an opioid, but has not tried the preferred alternatives, a denial should be issued and a maximum 60-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment. Additionally, a 6 month authorization should be entered for preferred products, depending on what the patient has already tried:</p> <ul style="list-style-type: none"> <li>• If the patient has tried morphine sulfate controlled release tablets (generic MS Contin) or preferred fentanyl transdermal, an authorization should be entered for hydrocodone extended-release capsules (generic Zohydro ER), methadone 5 mg tablets and methadone 10 mg tablets.</li> <li>• If the patient has not tried any of the preferred products [morphine sulfate controlled release tablets (generic MS Contin), preferred fentanyl transdermal, hydrocodone extended-release capsules (generic Zohydro ER), methadone 5 mg tablets or methadone 10 mg tablets], an authorization should be entered for morphine sulfate controlled release tablets (generic MS Contin) and preferred fentanyl transdermal.</li> </ul> |
|--|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                     |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name: tramadol ER, Conzip                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                     |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | 12 month(s)         |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1 - ONE of the following:</b></p> <p><b>1.1</b> The patient has failed a trial of tramadol IR (immediate release) as confirmed by claims history or submission of medical records</p> <p style="text-align: center;"><b>OR</b></p> <p><b>1.2</b> The patient has a history of contraindication or intolerance to tramadol IR (please specify contraindication or intolerance)</p> <p style="text-align: center;"><b>OR</b></p> <p><b>2 - BOTH of the following:</b></p> <p><b>2.1</b> ONE of the following:</p> |                     |

**2.1.1** Patient is being treated for cancer-related pain (i.e., patients undergoing active cancer treatment; or cancer survivors with chronic pain who have completed cancer treatment, are in clinical remission, or are under cancer surveillance)

**OR**

**2.1.2** Patient is in hospice or is receiving end of life care

**OR**

**2.1.3** Patient is being treated for sickle cell anemia related pain

**AND**

**2.2** BOTH of the following:

**2.2.1** Patient is established on pain therapy with the requested medication for cancer-related pain (i.e., patients undergoing active cancer treatment; or cancer survivors with chronic pain who have completed cancer treatment, are in clinical remission, or are under cancer surveillance), hospice related pain, sickle cell anemia related pain, or end of life care related pain

**AND**

**2.2.2** The medication is not a new regimen for treatment of cancer-related pain (i.e., patients undergoing active cancer treatment; or cancer survivors with chronic pain who have completed cancer treatment, are in clinical remission, or are under cancer surveillance), hospice, sickle cell anemia related pain, or end of life care pain (document date regimen was started)

Product Name:generic morphine sulfate ER/CR tabs, fentanyl patches, hydrocodone bitartrate ER caps, oxymorphone ER, morphine sulfate ER caps, hydromorphone ER, generic hydrocodone bitartrate ER tabs, Brand Hysingla ER, Brand MS Contin, Nucynta ER, Oxycodone ER, Oxycontin, Xtampza ER, methadone 5 mg or 10 mg tabs/soln, generic methadone conc, Brand Methadose conc, tramadol ER, Conzip, Brand Zohydro ER

|                |                |
|----------------|----------------|
| Guideline Type | Quantity Limit |
|----------------|----------------|

### Approval Criteria

1 - The requested dose cannot be achieved by moving to a higher strength of the product

**AND**

2 - The requested dose is within the Food and Drug Administration (FDA) maximum dose per day, where an FDA maximum dose per day exists

|       |                                                                                                                                                                                                                                                                                                                                                         |
|-------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Notes | <p>Authorization will be issued for:</p> <ul style="list-style-type: none"> <li>• 12 months for cancer/hospice/sickle cell anemia related pain/end of life related pain.</li> <li>• 12 months for all Tramadol ER requests.</li> <li>• 6 months for non-cancer/non-hospice/non-sickle cell anemia related pain/non-end of life related pain.</li> </ul> |
|-------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

Product Name:generic morphine sulfate ER/CR tabs, fentanyl patches, hydrocodone bitartrate ER caps, oxymorphone ER, morphine sulfate ER caps, hydromorphone ER, generic hydrocodone bitartrate ER tabs, Brand Hysingla ER, Brand MS Contin, Nucynta ER, Oxycodone ER, Oxycontin, Xtampza ER, methadone 5 mg or 10 mg tabs/soln, generic methadone conc, Brand Methadose conc, tramadol ER, Conzip, Brand Zohydro ER

|                 |                                                            |
|-----------------|------------------------------------------------------------|
| Diagnosis       | Cancer/Hospice/Sickle Cell Anemia/End of Life Related Pain |
| Approval Length | 12 Months*                                                 |
| Guideline Type  | Morphine Milligram Equivalent (MME)                        |

### Approval Criteria

1 - Doses exceeding the cumulative morphine milligram equivalent (MME) of 90 milligrams (mg) will be approved up to the requested amount for ALL opioid products if the patient has cancer-related pain (i.e., patients undergoing active cancer treatment; or cancer survivors with chronic pain who have completed cancer treatment, are in clinical remission, or are under cancer surveillance), hospice pain, end of life diagnosis, or sickle cell anemia

|       |                                                                                                                                                                                                                                                              |
|-------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Notes | <p>*Authorization will be issued for 12 months for cancer/hospice/sickle cell anemia/end of life related pain. The authorization should be entered for an MME of 9999 so as to prevent future disruptions in therapy if the patient's dose is increased.</p> |
|-------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                            |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------|
| Product Name:generic morphine sulfate ER/CR tabs, fentanyl patches, hydrocodone bitartrate ER caps, oxymorphone ER, morphine sulfate ER caps, hydromorphone ER, generic hydrocodone bitartrate ER tabs, Brand Hysingla ER, Brand MS Contin, Nucynta ER, Oxycodone ER, Oxycontin, Xtampza ER, methadone 5 mg or 10 mg tabs/soln, generic methadone conc, Brand Methadose conc, tramadol ER, Conzip, Brand Zohydro ER                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                            |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Non-cancer/non-hospice/non-sickle cell anemia/non-end of life related pain |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 6 Months*                                                                  |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Initial Authorization                                                      |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Morphine Milligram Equivalent (MME)                                        |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - If the dose exceeds the maximum cumulative morphine milligram equivalent (MME) of 90 mg, ALL of the following:</p> <p><b>1.1</b> Prescriber attests the patient has been screened for substance abuse/opioid dependence</p> <p style="text-align: center;"><b>AND</b></p> <p><b>1.2</b> Treatment goals are defined and include estimated duration of treatment (must document treatment goals)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>1.3</b> BOTH of the following:</p> <p><b>1.3.1</b> Patient has been screened for underlying depression and/or anxiety</p> <p style="text-align: center;"><b>AND</b></p> <p><b>1.3.2</b> If applicable, any underlying conditions have been or will be addressed</p> <p style="text-align: center;"><b>AND</b></p> <p><b>1.4</b> ONE of the following:</p> |                                                                            |

**1.4.1** Opioid medication doses of less than 90 MME have been tried and did not adequately control pain (document drug regimen or MME and dates of therapy)

**OR**

**1.4.2** Patient is new to plan and currently established on the requested MME for at least the past 30 days

|       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|-------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Notes | <p>*Authorization will be issued for 6 months for non-cancer/non-hospice/non-sickle cell anemia/non-end of life related pain up to the current requested MME plus 90 MME.</p> <p>If the patient has been established on the requested MME dose for at least 30 days and does not meet the medical necessity authorization criteria requirements, a denial should be issued and a maximum 60-day authorization may be authorized one time for the requested MME dose.</p> |
|-------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

Product Name:generic morphine sulfate ER/CR tabs, fentanyl patches, hydrocodone bitartrate ER caps, oxymorphone ER, morphine sulfate ER caps, hydromorphone ER, generic hydrocodone bitartrate ER tabs, Brand Hysingla ER, Brand MS Contin, Nucynta ER, Oxycodone ER, Oxycontin, Xtampza ER, methadone 5 mg or 10 mg tabs/soln, generic methadone conc, Brand Methadose conc, tramadol ER, Conzip, Brand Zohydro ER

|                 |                                                                            |
|-----------------|----------------------------------------------------------------------------|
| Diagnosis       | Non-cancer/non-hospice/non-sickle cell anemia/non-end of life related pain |
| Approval Length | 6 Months*                                                                  |
| Therapy Stage   | Reauthorization                                                            |
| Guideline Type  | Morphine Milligram Equivalent (MME)                                        |

### Approval Criteria

**1** - If the dose exceeds the maximum cumulative morphine milligram equivalent (MME) of 90 milligrams, ALL of the following:

**1.1** Prescriber attests the patient has been screened for substance abuse/opioid dependence

**AND**

**1.2** Document rationale for not tapering or discontinuing opioid if treatment goals are not being met

|                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>AND</b>                                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>1.3</b> Documented meaningful improvement in pain and function when assessed against treatment goals (document improvement in function or pain score improvement) |                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Notes                                                                                                                                                                | <p>*Authorization will be issued for 6 months for non-cancer/non-hospice/non-sickle cell anemia/non-end of life related pain up to the current requested MME plus 90 MME.</p> <p>If the patient has been established on the requested MME dose for at least 30 days and does not meet the medical necessity authorization criteria requirements, a denial should be issued and a maximum 60-day authorization may be authorized one time for the requested MME dose.</p> |

## 2 . Revision History

| Date      | Notes                                                                                                                                                                                  |
|-----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 5/14/2025 | Updated Oxycontin GPIs. Updated product names. Moved methadone tablets to preferred and oxymorphone ER to non-preferred. Updated notes in reference to updated PDL status of products. |



Lonhala and Yupelri



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-121003                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Guideline Name</b> | Lonhala and Yupelri                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 3/19/2023 |
|-----------------|-----------|

## 1 . Criteria

|                                                                    |                       |
|--------------------------------------------------------------------|-----------------------|
| Product Name:Lonhala Magnair (Starter Kit and Refill Kit), Yupelri |                       |
| Approval Length                                                    | 12 month(s)           |
| Therapy Stage                                                      | Initial Authorization |
| Guideline Type                                                     | Prior Authorization   |
|                                                                    |                       |

## Approval Criteria

**1** - Diagnosis of moderate to severe chronic obstructive pulmonary disease (COPD)

**AND**

**2** - ONE of the following:

**2.1** One of the following:

- Failure of Incruse Ellipta confirmed by claims history or submitted medical records
- History of intolerance or contraindication to Incruse Ellipta (please specify intolerance or contraindication)

**OR**

**2.2** BOTH of the following:

**2.2.1** Patient is unable to use a metered-dose, dry powder or slow mist inhaler (e.g. Incruse Ellipta) to control his/her COPD due to ONE of the following:

- Cognitive or physical impairment limiting coordination of handheld devices (e.g., cognitive decline, arthritis in the hands) (Document impairment)
- Patient is unable to generate adequate inspiratory force (e.g., peak inspiratory flow rate (PIFR) resistance is less than 60 liters per minute)

**AND**

**2.2.2** One of the following:

- Failure of ipratropium nebulized solution (generic Atrovent) confirmed by claims history or submitted medical records
- History of intolerance or contraindication to ipratropium nebulized solution (generic Atrovent) (please specify intolerance or contraindication)

|                                                                    |                     |
|--------------------------------------------------------------------|---------------------|
| Product Name:Lonhala Magnair (Starter Kit and Refill Kit), Yupelri |                     |
| Approval Length                                                    | 12 month(s)         |
| Therapy Stage                                                      | Reauthorization     |
| Guideline Type                                                     | Prior Authorization |

**Approval Criteria**

1 - Documentation of positive clinical response to therapy

**2 . Revision History**

| Date     | Notes      |
|----------|------------|
| 2/6/2023 | Removed TD |

Lonsurf



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-267204                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Guideline Name</b> | Lonsurf                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Washington (ACUWA, ACUWAAHE, ACUWAC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 7/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                      |                   |
|----------------------|-------------------|
| Product Name:Lonsurf |                   |
| Diagnosis            | Colorectal Cancer |
| Approval Length      | 12 month(s)       |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                       |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of advanced or metastatic colorectal cancer (mCRC)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - History of failure, contraindication, or intolerance to treatment with ALL of the following:</p> <ul style="list-style-type: none"> <li>• Fluoropyrimidine-based chemotherapy</li> <li>• Oxaliplatin-based chemotherapy</li> <li>• Irinotecan-based chemotherapy</li> <li>• Anti-vascular endothelial growth factor (VEGF) biological therapy</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - ONE of the following:</p> <p><b>3.1</b> Tumors is RAS mutant-type</p> <p style="text-align: center;"><b>OR</b></p> <p><b>3.2</b> BOTH of the following:</p> <ul style="list-style-type: none"> <li>• Tumor is RAS wild-type</li> <li>• History of failure, contraindication, or intolerance to anti-EGFR (epidermal growth factor receptor) therapy</li> </ul> |                       |

|                      |                                                  |
|----------------------|--------------------------------------------------|
| Product Name:Lonsurf |                                                  |
| Diagnosis            | Gastric/Gastroesophageal Junction Adenocarcinoma |
| Approval Length      | 12 month(s)                                      |
| Therapy Stage        | Initial Authorization                            |
| Guideline Type       | Prior Authorization                              |

### Approval Criteria

1 - Diagnosis of ONE of the following:

- Unresectable locally advanced, recurrent, or metastatic gastric cancer
- Unresectable locally advanced, recurrent, or metastatic gastroesophageal junction adenocarcinoma

**AND**

2 - History of failure, contraindication, or intolerance to treatment with at least TWO prior lines of chemotherapy that consisted of the following agents:

- Fluoropyrimidine (e.g., fluorouracil)
- Platinum (e.g., carboplatin, cisplatin, oxaliplatin)
- Taxane (e.g., docetaxel, paclitaxel) or irinotecan
- Human epidermal growth factor receptor 2 (HER2)/neu-targeted therapy (e.g., trastuzumab) (if HER2 overexpression)

| Product Name:Lonsurf                                                                                           |                                                                     |
|----------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------|
| Diagnosis                                                                                                      | Colorectal Cancer, Gastric/Gastroesophageal Junction Adenocarcinoma |
| Approval Length                                                                                                | 12 month(s)                                                         |
| Therapy Stage                                                                                                  | Reauthorization                                                     |
| Guideline Type                                                                                                 | Prior Authorization                                                 |
| <b>Approval Criteria</b><br>1 - Patient does not show evidence of progressive disease while on Lonsurf therapy |                                                                     |

| Product Name:Lonsurf |                           |
|----------------------|---------------------------|
| Diagnosis            | NCCN Recommended Regimens |
| Approval Length      | 12 month(s)               |

|                                                                                                                                                |                       |
|------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                                                                                  | Initial Authorization |
| Guideline Type                                                                                                                                 | Prior Authorization   |
| <b>Approval Criteria</b><br><br><b>1</b> - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium |                       |

|                                                                                                           |                           |
|-----------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Lonsurf                                                                                      |                           |
| Diagnosis                                                                                                 | NCCN Recommended Regimens |
| Approval Length                                                                                           | 12 month(s)               |
| Therapy Stage                                                                                             | Reauthorization           |
| Guideline Type                                                                                            | Prior Authorization       |
| <b>Approval Criteria</b><br><br><b>1</b> - Documentation of positive clinical response to Lonsurf therapy |                           |

## 2 . Revision History

| Date      | Notes               |
|-----------|---------------------|
| 5/15/2025 | Updated formularies |

Lorbrena



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-222191                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Guideline Name</b> | Lorbrena                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 5/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                       |                                    |
|-----------------------|------------------------------------|
| Product Name:Lorbrena |                                    |
| Diagnosis             | Non-Small Cell Lung Cancer (NSCLC) |
| Approval Length       | 12 month(s)                        |
| Therapy Stage         | Initial Authorization              |



| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Prior Authorization |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of non-small cell lung cancer (NSCLC)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - ONE of the following:</p> <p><b>2.1</b> Disease is BOTH of the following:</p> <ul style="list-style-type: none"> <li>• Recurrent, advanced, or metastatic</li> <li>• Anaplastic lymphoma kinase (ALK)-positive</li> </ul> <p style="text-align: center;"><b>OR</b></p> <p><b>2.2</b> BOTH of the following:</p> <p><b>2.2.1</b> Disease is BOTH of the following:</p> <ul style="list-style-type: none"> <li>• Recurrent, advanced, or metastatic</li> <li>• ROS proto-oncogene 1 (ROS1)-positive</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>2.2.2</b> Disease has progressed on at least ONE of the following therapies:</p> <ul style="list-style-type: none"> <li>• Augtyro (repotrectinib)</li> <li>• Rozlytrek (entrectinib)</li> <li>• Xalkori (crizotinib)</li> <li>• Zykadia (ceritinib)</li> </ul> |                     |

|                       |                       |
|-----------------------|-----------------------|
| Product Name:Lorbrena |                       |
| Diagnosis             | Histiocytic Neoplasms |
| Approval Length       | 12 month(s)           |

|                                                                                                                                                                                                                                                                                                   |                       |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                                                                                                                                                                                                                                     | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                    | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of Erdheim-Chester Disease (ECD)</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Disease is BOTH of the following:</p> <ul style="list-style-type: none"> <li>• Symptomatic, relapsed, or refractory</li> <li>• ALK-positive</li> </ul> |                       |

|                                                                                                                                                                                   |                       |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Lorbrena                                                                                                                                                             |                       |
| Diagnosis                                                                                                                                                                         | Soft Tissue Sarcoma   |
| Approval Length                                                                                                                                                                   | 12 month(s)           |
| Therapy Stage                                                                                                                                                                     | Initial Authorization |
| Guideline Type                                                                                                                                                                    | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of inflammatory myofibroblastic tumor (IMT)</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Disease is ALK-positive</p> |                       |

|                       |                 |
|-----------------------|-----------------|
| Product Name:Lorbrena |                 |
| Diagnosis             | Uterine Sarcoma |
| Approval Length       | 12 month(s)     |

|                                                                                                                                                                                                                                                                                                                                                                         |                       |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                           | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                          | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of uterine sarcoma</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Disease is ONE of the following:</p> <ul style="list-style-type: none"> <li>• Advanced</li> <li>• Recurrent/metastatic</li> <li>• Inoperable</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p>3 - Disease is ALK - positive</p> |                       |

|                                                                                                                                                                                                                                                     |                       |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Lorbrena                                                                                                                                                                                                                               |                       |
| Diagnosis                                                                                                                                                                                                                                           | Lymphoma              |
| Approval Length                                                                                                                                                                                                                                     | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                       | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                      | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - ONE of the following diagnoses:</p> <ul style="list-style-type: none"> <li>• Anaplastic large cell lymphoma (ALCL)</li> <li>• Large B-Cell lymphoma</li> </ul> <p style="text-align: center;"><b>AND</b></p> |                       |

**2** - Disease is relapsed or refractory

**AND**

**3** - Disease is ALK - positive

**Product Name:**Lorbrena

|           |                                                                                                           |
|-----------|-----------------------------------------------------------------------------------------------------------|
| Diagnosis | Non-Small Cell Lung Cancer (NSCLC), Histiocytic Neoplasms, Soft Tissue Sarcoma, Uterine Sarcoma, Lymphoma |
|-----------|-----------------------------------------------------------------------------------------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                 |
|---------------|-----------------|
| Therapy Stage | Reauthorization |
|---------------|-----------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

**1** - Patient does not show evidence of progressive disease while on Lorbrena therapy

**Product Name:**Lorbrena

|           |                          |
|-----------|--------------------------|
| Diagnosis | NCCN Recommended Regimen |
|-----------|--------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

**1** - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

**Product Name:**Lorbrena

|           |                          |
|-----------|--------------------------|
| Diagnosis | NCCN Recommended Regimen |
|-----------|--------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|                                                                                                     |                     |
|-----------------------------------------------------------------------------------------------------|---------------------|
| Therapy Stage                                                                                       | Reauthorization     |
| Guideline Type                                                                                      | Prior Authorization |
| <b>Approval Criteria</b><br><br>1 - Documentation of positive clinical response to Lorbrena therapy |                     |

## 2 . Revision History

| Date      | Notes                                                                                                                                                                 |
|-----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 3/24/2025 | Updated formularies. Added Augtyro (repotrectinib) as a first-line therapy option for ROS1 positive NSCLC per NCCN. Separated criteria in Soft Tissue Sarcoma section |

Lucemyra



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|-----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-267205                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Guideline Name</b> | Lucemyra                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 7/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                                                                              |                     |
|------------------------------------------------------------------------------|---------------------|
| Product Name: Brand Lucemyra, generic lofexidine                             |                     |
| Approval Length                                                              | 14 Day(s)           |
| Guideline Type                                                               | Prior Authorization |
| <b>Approval Criteria</b><br><br>1 - For symptoms of abrupt opioid withdrawal |                     |

|                                                                                                                                                                                                                                                           |                                                                                                                                                                  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>AND</b>                                                                                                                                                                                                                                                |                                                                                                                                                                  |
| <b>2</b> - Opioids have been discontinued                                                                                                                                                                                                                 |                                                                                                                                                                  |
| <b>AND</b>                                                                                                                                                                                                                                                |                                                                                                                                                                  |
| <b>3</b> - ONE of the following:                                                                                                                                                                                                                          |                                                                                                                                                                  |
| <b>3.1</b> ONE of the following:                                                                                                                                                                                                                          |                                                                                                                                                                  |
| <ul style="list-style-type: none"> <li>• Failure to clonidine confirmed by claims history or submission of medical records</li> <li>• History of contraindication or intolerance to clonidine (please specify intolerance or contraindication)</li> </ul> |                                                                                                                                                                  |
| <b>OR</b>                                                                                                                                                                                                                                                 |                                                                                                                                                                  |
| <b>3.2</b> Lucemyra was initiated in the inpatient setting*                                                                                                                                                                                               |                                                                                                                                                                  |
| Notes                                                                                                                                                                                                                                                     | *Authorization will be issued for 14 days of therapy. If Lucemyra was initiated in the inpatient setting, the total course of therapy should not exceed 14 days. |

## 2 . Revision History

| Date      | Notes                       |
|-----------|-----------------------------|
| 5/16/2025 | Updated GPIs to add generic |

Lumakras



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-425232                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Guideline Name</b> | Lumakras                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Washington (ACUWA, ACUWAAHE, ACUWAC)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 11/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                       |                                    |
|-----------------------|------------------------------------|
| Product Name:Lumakras |                                    |
| Diagnosis             | Non-Small Cell Lung Cancer (NSCLC) |
| Approval Length       | 12 month(s)                        |



|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                       |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of non-small cell lung cancer (NSCLC)</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Disease is ONE of the following:</p> <ul style="list-style-type: none"> <li>• Recurrent</li> <li>• Advanced</li> <li>• Metastatic</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p>3 - Tumor is KRAS G12C-mutation positive</p> <p style="text-align: center;"><b>AND</b></p> <p>4 - Patient has received at least one prior systemic therapy (e.g., immune checkpoint inhibitor, platinum-based chemotherapy)</p> |                       |

|                                                                                   |                           |
|-----------------------------------------------------------------------------------|---------------------------|
| Product Name:Lumakras                                                             |                           |
| Diagnosis                                                                         | Pancreatic Adenocarcinoma |
| Approval Length                                                                   | 12 month(s)               |
| Therapy Stage                                                                     | Initial Authorization     |
| Guideline Type                                                                    | Prior Authorization       |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of pancreatic adenocarcinoma</p> |                           |

**AND**

**2** - Disease is ONE of the following:

- Recurrent
- Locally advanced
- Metastatic

**AND**

**3** - Tumor is KRAS G12C-mutation positive

**AND**

**4** - Patient has received at least one prior systemic therapy (e.g., immune checkpoint inhibitor, platinum-based chemotherapy)

Product Name:Lumakras

|           |                          |
|-----------|--------------------------|
| Diagnosis | Ampullary Adenocarcinoma |
|-----------|--------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

### Approval Criteria

**1** - Diagnosis of ampullary adenocarcinoma

**AND**

**2** - Disease is progressive

**AND**

**3** - Tumor is KRAS G12C-mutation positive

**AND**

**4** - Patient has received at least one prior systemic therapy (e.g., immune checkpoint inhibitor, platinum-based chemotherapy)

**Product Name:**Lumakras

|           |              |
|-----------|--------------|
| Diagnosis | Colon Cancer |
|-----------|--------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

**1** - Diagnosis of colon cancer

**AND**

**2** - Tumor is KRAS G12C-mutation positive

**AND**

**3** - Patient has received at least one prior systemic therapy (e.g., immune checkpoint inhibitor, platinum-based chemotherapy)

**Product Name:**Lumakras

|           |               |
|-----------|---------------|
| Diagnosis | Rectal Cancer |
|-----------|---------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|                                                                                                                                                                                                                                                                                                                                                        |                       |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                                                                                                                                                                                                                                                                                          | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                         | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of rectal cancer</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Tumor is KRAS G12C-mutation positive</p> <p style="text-align: center;"><b>AND</b></p> <p>3 - Patient has received at least one prior systemic therapy (e.g., immune checkpoint inhibitor, platinum-based chemotherapy)</p> |                       |

|                                                                                                                                                                                                         |                                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|
| Product Name:Lumakras                                                                                                                                                                                   |                                |
| Diagnosis                                                                                                                                                                                               | Central Nervous System Cancers |
| Approval Length                                                                                                                                                                                         | 12 month(s)                    |
| Therapy Stage                                                                                                                                                                                           | Initial Authorization          |
| Guideline Type                                                                                                                                                                                          | Prior Authorization            |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of brain metastases</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Metastases from KRAS G12C-mutated positive non-small cell lung cancer</p> |                                |

|                       |
|-----------------------|
| Product Name:Lumakras |
|-----------------------|

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                            |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Small Bowel Adenocarcinoma |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 12 month(s)                |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Initial Authorization      |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Prior Authorization        |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of small bowel adenocarcinoma</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Disease is ONE of the following:</p> <ul style="list-style-type: none"> <li>• Advanced</li> <li>• Metastatic</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Tumor is KRAS G12C-mutation positive</p> <p style="text-align: center;"><b>AND</b></p> <p><b>4</b> - Patient has received at least one prior systemic therapy (e.g., immune checkpoint inhibitor, platinum-based chemotherapy)</p> |                            |

|                       |                                                                                                                                                                                  |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Product Name:Lumakras |                                                                                                                                                                                  |
| Diagnosis             | Non-Small Cell Lung Cancer (NSCLC), Pancreatic Adenocarcinoma, Ampullary Adenocarcinoma, Colon Cancer, Rectal Cancer, Central Nervous System Cancers, Small Bowel Adenocarcinoma |
| Approval Length       | 12 month(s)                                                                                                                                                                      |
| Therapy Stage         | Reauthorization                                                                                                                                                                  |
| Guideline Type        | Prior Authorization                                                                                                                                                              |

**Approval Criteria**

1 - Patient does not show evidence of progressive disease while on Lumakras therapy

Product Name:Lumakras

|           |                           |
|-----------|---------------------------|
| Diagnosis | NCCN Recommended Regimens |
|-----------|---------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Lumakras

|           |                           |
|-----------|---------------------------|
| Diagnosis | NCCN Recommended Regimens |
|-----------|---------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                 |
|---------------|-----------------|
| Therapy Stage | Reauthorization |
|---------------|-----------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

1 - Documentation of positive clinical response to Lumakras therapy

## 2 . Revision History

|      |       |
|------|-------|
| Date | Notes |
|------|-------|

|            |                                                                            |
|------------|----------------------------------------------------------------------------|
| 10/21/2025 | Updated formularies to include IN for eff 11/1/25. Minor cosmetic updates. |
|------------|----------------------------------------------------------------------------|

Lupkynis



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-371233                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Guideline Name</b> | Lupkynis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Michigan (ACUMI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 9/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                       |                       |
|-----------------------|-----------------------|
| Product Name:Lupkynis |                       |
| Approval Length       | 12 month(s)           |
| Therapy Stage         | Initial Authorization |



| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Prior Authorization |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1 - Diagnosis of active lupus nephritis</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>2 - Provider attests to ONE of the following:</b></p> <ul style="list-style-type: none"> <li>• Diagnosis is biopsy proven</li> <li>• Biopsy is contraindicated in the patient</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>3 - Provider attests to ONE of the following:</b></p> <p><b>3.1</b> Clinical progression (e.g., worsening of proteinuria or serum creatinine) after 3 months of induction therapy with immunosuppressive agents (e.g., mycophenolate, cyclophosphamide, methylprednisolone), as confirmed by claims history or submission of medical records</p> <p style="text-align: center;"><b>OR</b></p> <p><b>3.2</b> Failure to respond after 6 months of induction therapy with immunosuppressive agents (e.g., mycophenolate, cyclophosphamide, methylprednisolone), as confirmed by claims history or submission of medical records</p> <p style="text-align: center;"><b>AND</b></p> <p><b>4 - Prescribed in combination with a background immunosuppressive therapy regimen (e.g., mycophenolate mofetil and corticosteroids)</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>5 - Patient is NOT receiving Lupkynis in combination with either of the following:</b></p> |                     |

- Cyclophosphamide
- Benlysta (belimumab)

**AND**

**6** - Prescribed by ONE of the following:

- Nephrologist
- Rheumatologist

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                     |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Lupkynis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                     |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 12 month(s)         |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of positive clinical response to Lupkynis therapy</p> <p><b>AND</b></p> <p><b>2</b> - Prescribed in combination with a background immunosuppressive therapy regimen (e.g., mycophenolate mofetil and corticosteroids)</p> <p><b>AND</b></p> <p><b>3</b> - Patient is NOT receiving Lupkynis in combination with either of the following:</p> <ul style="list-style-type: none"> <li>• Cyclophosphamide</li> <li>• Benlysta (belimumab)</li> </ul> <p><b>AND</b></p> |                     |

**4** - Prescribed by ONE of the following:

- Nephrologist
- Rheumatologist

## **2 . Revision History**

| Date      | Notes                                           |
|-----------|-------------------------------------------------|
| 8/18/2025 | Updated re-auth criteria. Combined formularies. |

Lynparza



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-430188                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Guideline Name</b> | Lynparza                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Washington (ACUWA, ACUWAAHE, ACUWAC)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 11/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                       |                                 |
|-----------------------|---------------------------------|
| Product Name:Lynparza |                                 |
| Diagnosis             | Breast Cancer (High Risk Early) |
| Approval Length       | 12 month(s)                     |

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Prior Authorization |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of high risk early breast cancer</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Presence of deleterious or suspected deleterious germline breast cancer (BRCA)-mutations (gBRCAm)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Disease is human growth factor receptor 2 (HER2)-negative</p> <p style="text-align: center;"><b>AND</b></p> <p><b>4</b> - ONE of the following:</p> <p style="padding-left: 20px;"><b>4.1</b> Patient is hormone receptor (HR) negative</p> <p style="text-align: center;"><b>OR</b></p> <p style="padding-left: 20px;"><b>4.2</b> BOTH of the following:</p> <p style="padding-left: 40px;"><b>4.2.1</b> Patient is hormone receptor (HR) positive</p> <p style="text-align: center;"><b>AND</b></p> <p style="padding-left: 40px;"><b>4.2.2</b> Patient is continuing concurrent treatment with endocrine therapy</p> <p style="text-align: center;"><b>AND</b></p> <p><b>5</b> - Patient has been treated with neoadjuvant or adjuvant chemotherapy</p> |                     |

**AND**

**6** - Treatment duration has not exceeded 12 months of therapy

Product Name:Lynparza

|           |                                         |
|-----------|-----------------------------------------|
| Diagnosis | Breast Cancer (Metastatic or Recurrent) |
|-----------|-----------------------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

### Approval Criteria

**1** - Diagnosis of ONE of the following:

**1.1** Metastatic breast cancer

**OR**

**1.2** Recurrent breast cancer

**AND**

**2** - Presence of deleterious or suspected deleterious germline breast cancer (BRCA)-mutations (gBRCAm)

**AND**

**3** - ONE of the following:

**3.1** BOTH of the following:

**3.1.1** Disease is human epidermal growth factor receptor 2 (HER2)-negative

**AND**

**3.1.2** ONE of the following:

**3.1.2.1** Disease is hormone receptor (HR) negative

**OR**

**3.1.2.2** BOTH of the following:

**3.1.2.2.1** Disease is hormone receptor (HR) positive

**AND**

**3.1.2.2.2** ONE of the following:

- Disease has progressed on previous endocrine therapy
- Provider attestation that treatment with endocrine therapy is inappropriate

**OR**

**3.2** Disease is human epidermal growth factor receptor 2 (HER2)-positive

|                                                                                      |                                      |
|--------------------------------------------------------------------------------------|--------------------------------------|
| Product Name:Lynparza                                                                |                                      |
| Diagnosis                                                                            | Ovarian Cancer (Maintenance Therapy) |
| Approval Length                                                                      | 12 month(s)                          |
| Therapy Stage                                                                        | Initial Authorization                |
| Guideline Type                                                                       | Prior Authorization                  |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of ONE of the following:</p> |                                      |

- Epithelial ovarian cancer
- Fallopian tube cancer
- Primary peritoneal cancer

**AND**

**2** - Disease is ONE of the following:

- Advanced
- Recurrent

**AND**

**3** - ONE of the following:

**3.1** Presence of deleterious or suspected deleterious germline or somatic BRCA-mutations

**OR**

**3.2** BOTH of the following:

**3.2.1** Cancer is associated with homologous recombination deficiency (HRD)-positive status defined by either a deleterious or suspected deleterious BRCA mutation or genomic instability

**AND**

**3.2.2** Used in combination with bevacizumab (e.g., Avastin, Mvasi)

**AND**

**4** - Patient has had a complete or partial response to platinum-based chemotherapy

**AND**

**5** - Request is for maintenance therapy



|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                            |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|
| Product Name:Lynparza                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                            |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Ovarian Cancer (Treatment) |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 12 month(s)                |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Initial Authorization      |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Prior Authorization        |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of ONE of the following:</p> <ul style="list-style-type: none"> <li>• Epithelial ovarian cancer</li> <li>• Fallopian tube cancer</li> <li>• Primary peritoneal cancer</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Disease is ONE of the following:</p> <ul style="list-style-type: none"> <li>• Advanced</li> <li>• Persistent</li> <li>• Recurrent</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Presence of deleterious or suspected deleterious germline BRCA (breast cancer gene)-mutation</p> <p style="text-align: center;"><b>AND</b></p> <p><b>4</b> - Patient has been treated with two or more prior lines of chemotherapy</p> |                            |

|                       |                       |
|-----------------------|-----------------------|
| Product Name:Lynparza |                       |
| Diagnosis             | Pancreatic Cancer     |
| Approval Length       | 12 month(s)           |
| Therapy Stage         | Initial Authorization |

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Prior Authorization |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of pancreatic adenocarcinoma</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Disease is metastatic</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Presence of deleterious or suspected deleterious germline BRCA1/2 (breast cancer gene)-mutation</p> <p style="text-align: center;"><b>AND</b></p> <p><b>4</b> - Disease has NOT progressed while receiving at least 16 weeks of a first-line platinum-based chemotherapy regimen</p> |                     |

|                                                                                                                                                              |                       |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Lynparza                                                                                                                                        |                       |
| Diagnosis                                                                                                                                                    | Prostate Cancer       |
| Approval Length                                                                                                                                              | 12 month(s)           |
| Therapy Stage                                                                                                                                                | Initial Authorization |
| Guideline Type                                                                                                                                               | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of metastatic castration-resistant prostate cancer</p> <p style="text-align: center;"><b>AND</b></p> |                       |

**2 - ONE of the following:**

**2.1 BOTH of the following:**

**2.1.1** Presence of deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene mutations

**AND**

**2.1.2** Disease has progressed following prior treatment with ONE of the following:

- Enzalutamide (Xtandi)
- Abiraterone (e.g., Zytiga, Yonsa)

**OR**

**2.2 ALL of the following:**

**2.2.1** Presence of deleterious or suspected deleterious BRCA-mutation

**AND**

**2.2.2** Used in combination with abiraterone (e.g., Zytiga, Yonsa)

**AND**

**2.2.3** Used in combination with steroids (e.g., methylprednisolone, prednisolone, prednisone)

**AND**

**3 - ONE of the following:**

**3.1** Used in combination with a gonadotropin-releasing hormone (GnRH) analog [e.g., Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix)]

**OR**

**3.2 Patient has had bilateral orchiectomy**

|                                                                                                                                                                                             |                       |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Lynparza                                                                                                                                                                       |                       |
| Diagnosis                                                                                                                                                                                   | Uterine Neoplasms     |
| Approval Length                                                                                                                                                                             | 12 month(s)           |
| Therapy Stage                                                                                                                                                                               | Initial Authorization |
| Guideline Type                                                                                                                                                                              | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of uterine sarcoma</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - The requested medication is NOT used as first-line therapy</p> |                       |

|                                                                                                                            |                                                                                                                                           |
|----------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------|
| Product Name:Lynparza                                                                                                      |                                                                                                                                           |
| Diagnosis                                                                                                                  | Breast Cancer (Metastatic or Recurrent), Ovarian Cancer (Maintenance or Treatment), Pancreatic Cancer, Prostate Cancer, Uterine Neoplasms |
| Approval Length                                                                                                            | 12 month(s)                                                                                                                               |
| Therapy Stage                                                                                                              | Reauthorization                                                                                                                           |
| Guideline Type                                                                                                             | Prior Authorization                                                                                                                       |
| <p><b>Approval Criteria</b></p> <p>1 - Patient does not show evidence of progressive disease while on Lynparza therapy</p> |                                                                                                                                           |

|                       |                          |
|-----------------------|--------------------------|
| Product Name:Lynparza |                          |
| Diagnosis             | NCCN Recommended Regimen |
| Approval Length       | 12 month(s)              |

|                                                                                                                                                |                       |
|------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                                                                                  | Initial Authorization |
| Guideline Type                                                                                                                                 | Prior Authorization   |
| <b>Approval Criteria</b><br><br><b>1</b> - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium |                       |

|                                                                                                            |                          |
|------------------------------------------------------------------------------------------------------------|--------------------------|
| Product Name:Lynparza                                                                                      |                          |
| Diagnosis                                                                                                  | NCCN Recommended Regimen |
| Approval Length                                                                                            | 12 month(s)              |
| Therapy Stage                                                                                              | Reauthorization          |
| Guideline Type                                                                                             | Prior Authorization      |
| <b>Approval Criteria</b><br><br><b>1</b> - Documentation of positive clinical response to Lynparza therapy |                          |

## 2 . Revision History

| Date       | Notes                                                                      |
|------------|----------------------------------------------------------------------------|
| 10/23/2025 | Updated formularies to include IN for eff 11/1/25. Minor cosmetic updates. |

Lyrica



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-164978                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Guideline Name</b> | Lyrica                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 3/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                           |                     |
|---------------------------|---------------------|
| Product Name:Brand Lyrica |                     |
| Approval Length           | 12 month(s)         |
| Guideline Type            | Prior Authorization |
| Approval Criteria         |                     |

**1** - Requested for the treatment of a seizure disorder

**OR**

**2** - BOTH of the following:

**2.1** Diagnosis of ONE of the following:

- Fibromyalgia
- Diabetic peripheral neuropathy (DPN)
- Post herpetic neuralgia (PHN)
- Neuropathic pain associated with spinal cord injury

**AND**

**2.2** ONE of the following:

**2.2.1** Failure to generic pregabalin at a minimum dose of 300 mg (milligrams) daily for 4 weeks as confirmed by claims history or submission of medical records

**OR**

**2.2.2** History of intolerance or contraindication to generic pregabalin (please specify intolerance or contraindication)

|                                                                                                     |                                      |
|-----------------------------------------------------------------------------------------------------|--------------------------------------|
| Product Name: Brand Lyrica CR, generic pregabalin ER                                                |                                      |
| Diagnosis                                                                                           | Diabetic Peripheral Neuropathy (DPN) |
| Approval Length                                                                                     | 12 month(s)                          |
| Guideline Type                                                                                      | Prior Authorization                  |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of diabetic peripheral neuropathy (DPN)</p> |                                      |

**AND**

**2 - ONE of the following:**

**2.1** Failure to gabapentin (generic Neurontin) at a minimum dose of 1800 mg daily for 4 weeks as confirmed by claims history or submission of medical records

**OR**

**2.2** History of intolerance or contraindication to gabapentin (generic Neurontin) (please specify intolerance or contraindication)

**AND**

**3 - ONE of the following:**

**3.1** Failure to treatment with ONE of the following classes of medications as confirmed by claims history or submission of medical records:

- Tricyclic antidepressant at the maximum tolerated dose for 6 to 8 weeks, or intolerance to a tricyclic antidepressant
- Serotonin and norepinephrine reuptake inhibitor (SNRI) antidepressant (e.g., duloxetine, venlafaxine)

**OR**

**3.2** History of intolerance or contraindication to treatment from BOTH classes of medications (please specify intolerance or contraindication)

- Tricyclic antidepressant at the maximum tolerated dose for 6 to 8 weeks, or intolerance to a tricyclic antidepressant
- SNRI antidepressant (e.g., duloxetine, venlafaxine)

**AND**

**4 - ONE of the following:**



**4.1** Failure to generic pregabalin immediate-release capsules or generic pregabalin suspension as confirmed by claims history or submission of medical records

**OR**

**4.2** History of intolerance or contraindication to generic pregabalin immediate-release capsules or generic pregabalin suspension (please specify intolerance or contraindication)

Product Name: Brand Lyrica CR, generic pregabalin ER

|           |                               |
|-----------|-------------------------------|
| Diagnosis | Post Herpetic Neuralgia (PHN) |
|-----------|-------------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

**1** - Diagnosis of post herpetic neuralgia (PHN)

**AND**

**2** - ONE of the following:

**2.1** Failure to gabapentin (generic Neurontin) at a minimum dose of 1800 mg daily for 4 weeks as confirmed by claims history or submission of medical records

**OR**

**2.2** History of intolerance or contraindication to gabapentin (generic Neurontin) (please specify intolerance or contraindication)

**AND**

**3** - ONE of the following:

**3.1** Failure to a tricyclic antidepressant at the maximum tolerated dose for 6 to 8 weeks as confirmed by claims history of submission of medical records

**OR**

**3.2** History of intolerance or contraindication to a tricyclic antidepressant (please specify intolerance or contraindication)

**AND**

**4** - ONE of the following:

**4.1** Failure to generic pregabalin immediate-release capsules or generic pregabalin suspension as confirmed by claims history or submission of medical records

**OR**

**4.2** History of intolerance or contraindication to generic pregabalin immediate-release capsules or generic pregabalin suspension (please specify intolerance or contraindication)

## 2 . Revision History

| Date      | Notes               |
|-----------|---------------------|
| 2/11/2025 | Updated formularies |

Lysteda



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-159421                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Guideline Name</b> | Lysteda                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>•</li> <li>•</li> <li>•</li> <li>•</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 1/1/2023 |
|-----------------|----------|

## 1 . Criteria

|                                                      |                     |
|------------------------------------------------------|---------------------|
| Product Name: Brand Lysteda, generic tranexamic acid |                     |
| Approval Length                                      | 12 month(s)         |
| Guideline Type                                       | Prior Authorization |

**Approval Criteria**

1 - Diagnosis of cyclic heavy menstrual bleeding

**2 . Revision History**

| Date      | Notes                                                     |
|-----------|-----------------------------------------------------------|
| 11/7/2024 | Updated Markets in Scope. No changes to clinical criteria |

Lytgobi



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-163892                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Guideline Name</b> | Lytgobi                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 2/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                      |                       |
|----------------------|-----------------------|
| Product Name:Lytgobi |                       |
| Diagnosis            | Cholangiocarcinoma    |
| Approval Length      | 12 month(s)           |
| Therapy Stage        | Initial Authorization |
| Guideline Type       | Prior Authorization   |

**Approval Criteria**

**1** - Diagnosis of cholangiocarcinoma (intrahepatic or extrahepatic)

**AND**

**2** - Disease is ONE of the following:

- Unresectable
- Resected gross residual (R2)
- Metastatic

**AND**

**3** - Positive for fibroblast growth factor receptor 2 (FGFR2) fusions or rearrangements

**AND**

**4** - Used as second line or subsequent treatment

|                                                                                                                                  |                     |
|----------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Lytgobi                                                                                                             |                     |
| Diagnosis                                                                                                                        | Cholangiocarcinoma  |
| Approval Length                                                                                                                  | 12 month(s)         |
| Therapy Stage                                                                                                                    | Reauthorization     |
| Guideline Type                                                                                                                   | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Patient does not show evidence of progressive disease while on Lytgobi therapy</p> |                     |

|                      |
|----------------------|
| Product Name:Lytgobi |
|----------------------|

|                                                                                                                                                |                           |
|------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Diagnosis                                                                                                                                      | NCCN Recommended Regimens |
| Approval Length                                                                                                                                | 12 month(s)               |
| Therapy Stage                                                                                                                                  | Initial Authorization     |
| Guideline Type                                                                                                                                 | Prior Authorization       |
| <b>Approval Criteria</b><br><br><b>1</b> - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium |                           |

|                                                                                                           |                           |
|-----------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Lytgobi                                                                                      |                           |
| Diagnosis                                                                                                 | NCCN Recommended Regimens |
| Approval Length                                                                                           | 12 month(s)               |
| Therapy Stage                                                                                             | Reauthorization           |
| Guideline Type                                                                                            | Prior Authorization       |
| <b>Approval Criteria</b><br><br><b>1</b> - Documentation of positive clinical response to Lytgobi therapy |                           |

## 2 . Revision History

| Date      | Notes                                       |
|-----------|---------------------------------------------|
| 1/16/2025 | Updated cholangiocarcinoma initial criteria |

Marinol, Syndros



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-161398                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Guideline Name</b> | Marinol, Syndros                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 1/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                       |                                          |
|-----------------------|------------------------------------------|
| Product Name: Syndros |                                          |
| Diagnosis             | Chemotherapy-induced nausea and vomiting |
| Approval Length       | 12 month(s)                              |
| Guideline Type        | Prior Authorization                      |
|                       |                                          |



**Approval Criteria**

**1** - Patient is receiving cancer chemotherapy

**AND**

**2** - ONE of the following:

**2.1** Failure to formulary generic dronabinol as confirmed by claims history or submission of medical records

**OR**

**2.2** History of contraindication or intolerance to formulary generic dronabinol (please specify contraindication or intolerance)

**OR**

**2.3** Patient is unable to swallow capsules

**AND**

**3** - ONE of the following:

**3.1** Failure to a 5HT-3 (5-hydroxytryptamine type 3) receptor antagonist [e.g., Anzemet (dolasetron), Kytril (granisetron), or Zofran (ondansetron)] as confirmed by claims history or submission of medical records

**OR**

**3.2** History of contraindication or intolerance to a 5HT-3 receptor antagonist [e.g., Anzemet (dolasetron), Kytril (granisetron), or Zofran (ondansetron)] (please specify contraindication or intolerance)

**AND**

**4** - ONE of the following:

**4.1** Failure to ONE of the following as confirmed by claims history or submission of medical records:

- Lorazepam (generic Ativan)
- Prochlorperazine (generic Compazine)
- Dexamethasone (generic Decadron)
- Haloperidol (generic Haldol)
- Promethazine (generic Phenergan)
- Metoclopramide (generic Reglan)
- Olanzapine (generic Zyprexa)

**OR**

**4.2** History of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):

- Lorazepam (generic Ativan)
- Prochlorperazine (generic Compazine)
- Dexamethasone (generic Decadron)
- Haloperidol (generic Haldol)
- Promethazine (generic Phenergan)
- Metoclopramide (generic Reglan)
- Olanzapine (generic Zyprexa)

|                                                                                                                                                                                    |                                          |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------|
| <b>Product Name:</b> Brand Marinol, generic dronabinol                                                                                                                             |                                          |
| <b>Diagnosis</b>                                                                                                                                                                   | Chemotherapy-induced nausea and vomiting |
| <b>Approval Length</b>                                                                                                                                                             | 12 month(s)                              |
| <b>Guideline Type</b>                                                                                                                                                              | Prior Authorization                      |
| <p><b>Approval Criteria</b></p> <p>1 - Patient is receiving cancer chemotherapy</p> <p style="text-align: center; margin: 20px 0;"><b>AND</b></p> <p>2 - ONE of the following:</p> |                                          |

**2.1** Failure to a 5HT-3 (5-hydroxytryptamine type 3) receptor antagonist [e.g., Anzemet (dolasetron), Kytril (granisetron), or Zofran (ondansetron)] as confirmed by claims history or submission of medical records

**OR**

**2.2** History of contraindication or intolerance to a 5HT-3 receptor antagonist [e.g., Anzemet (dolasetron), Kytril (granisetron), or Zofran (ondansetron)] (please specify contraindication or intolerance)

**AND**

**3** - ONE of the following:

**3.1** Failure to ONE of the following as confirmed by claims history or submission of medical records:

- Lorazepam (generic Ativan)
- Prochlorperazine (generic Compazine)
- Dexamethasone (generic Decadron)
- Haloperidol (generic Haldol)
- Promethazine (generic Phenergan)
- Metoclopramide (generic Reglan)
- Olanzapine (generic Zyprexa)

**OR**

**3.2** History of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):

- Lorazepam (generic Ativan)
- Prochlorperazine (generic Compazine)
- Dexamethasone (generic Decadron)
- Haloperidol (generic Haldol)
- Promethazine (generic Phenergan)
- Metoclopramide (generic Reglan)
- Olanzapine (generic Zyprexa)

Product Name:Syndros

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Anorexia in a patient with AIDS |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 12 month(s)                     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Prior Authorization             |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of anorexia with weight loss in a patient with AIDS (acquired immunodeficiency syndrome)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Patient is on antiretroviral therapy</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - ONE of the following:</p> <p style="padding-left: 20px;"><b>3.1</b> Patient is 65 years of age or greater</p> <p style="text-align: center;"><b>OR</b></p> <p style="padding-left: 20px;"><b>3.2</b> BOTH of the following:</p> <p style="padding-left: 40px;"><b>3.2.1</b> Patient is less than 65 years of age</p> <p style="text-align: center;"><b>AND</b></p> <p style="padding-left: 40px;"><b>3.2.2</b> ONE of the following:</p> <p style="padding-left: 60px;"><b>3.2.2.1</b> Failure to megestrol (generic Megace) as confirmed by claims history or submission of medical records</p> <p style="text-align: center;"><b>OR</b></p> |                                 |

**3.2.2.2** History of intolerance or contraindication to megestrol (generic Megace) (please specify intolerance or contraindication)

**AND**

**4** - ONE of the following:

**4.1** Failure to formulary generic dronabinol as confirmed by claims history or submission of medical records

**OR**

**4.2** History of contraindication or intolerance to formulary generic dronabinol (please specify contraindication or intolerance)

**OR**

**4.3** Patient is unable to swallow capsules

Product Name: Brand Marinol, generic dronabinol

|           |                                 |
|-----------|---------------------------------|
| Diagnosis | Anorexia in a patient with AIDS |
|-----------|---------------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

**1** - Diagnosis of anorexia with weight loss in a patient with AIDS (acquired immunodeficiency syndrome)

**AND**

**2** - Patient is on antiretroviral therapy

**AND**

**3 - ONE of the following:**

**3.1** Patient is 65 years of age or greater

**OR**

**3.2 BOTH of the following:**

**3.2.1** Patient is less than 65 years of age

**AND**

**3.2.2 ONE of the following:**

**3.2.2.1** Failure to megestrol (generic Megace) as confirmed by claims history or submission of medical records

**OR**

**3.2.2.2** History of intolerance or contraindication to megestrol (generic Megace) (please specify intolerance or contraindication)

## 2 . Revision History

| Date       | Notes                                                                                                                               |
|------------|-------------------------------------------------------------------------------------------------------------------------------------|
| 11/27/2024 | Added GPIs for Brand Marinol capsules 5mg and 10mg strengths. Minor update to 5HT-3 definition, with no changes to clinical intent. |

Mavenclad



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-249188                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Guideline Name</b> | Mavenclad                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 7/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                        |                       |
|------------------------|-----------------------|
| Product Name:Mavenclad |                       |
| Approval Length        | 2 month(s)            |
| Therapy Stage          | Initial Authorization |
| Guideline Type         | Prior Authorization   |

### **Approval Criteria**

**1** - Diagnosis of relapsing form of multiple sclerosis (MS) (e.g., relapsing-remitting MS, secondary progressive MS with relapses)

**AND**

**2** - Prescribed by, or in consultation with, a specialist in the treatment of MS (e.g., neurologist)

**AND**

**3** - ONE of the following:

**3.1** Trial and failure (after trial of at least 4 weeks) to TWO of the following disease-modifying therapies for MS (one of which must be a preferred dimethyl fumarate product) as confirmed by claims history or submission of medical records:

- Interferon beta-1a (Avonex\*, Rebif\*, Plegridy)
- Interferon beta-1b (Betaseron\*, Extavia\*)
- Glatiramer acetate products (e.g., Copaxone, Glatopa)
- A preferred dimethyl fumarate product (e.g., Tecfidera)
- Teriflunomide (generic Aubagio)
- Fingolimod (generic Gilenya)
- Mayzent (siponimod)
- Tyruko (natalizumab-sztn)\*\*
- Tysabri (natalizumab)\*\*
- Ocrevus (ocrelizumab)\*\*
- Lemtrada (alemtuzumab)\*\*
- Zeposia (ozanimod)\*
- Kesimpta (ofatumumab)\*
- Bafiertam (monomethyl fumarate)\*
- Briumvi (ublituximab)\*\*

**OR**

**3.2** History of contraindication or intolerance to TWO of the following disease-modifying therapies for MS (please specify contraindication or intolerance)

- Interferon beta-1a (Avonex\*, Rebif\*, Plegridy)
- Interferon beta-1b (Betaseron\*, Extavia\*)



- Glatiramer acetate products (e.g., Copaxone, Glatopa)
- A preferred dimethyl fumarate product (e.g., Tecfidera)
- Teriflunomide (generic Aubagio)
- Fingolimod (generic Gilenya)
- Mayzent (siponimod)
- Tyruko (natalizumab-sztn)\*\*
- Tysabri (natalizumab)\*\*
- Ocrevus (ocrelizumab)\*\*
- Lemtrada (alemtuzumab)\*\*
- Zeposia (ozanimod)\*
- Kesimpta (ofatumumab)\*
- Bafiertam (monomethyl fumarate)\*
- Briumvi (ublituximab)\*\*

**OR**

**3.3** Patient is currently on Mavenclad

**AND**

**4** - Patient is NOT receiving Mavenclad in combination with another disease modifying therapy [e.g., interferon beta preparations, glatiramer acetate products, Tecfidera (dimethyl fumarate), Tysabri (natalizumab), Gilenya (fingolimod), Mayzent (siponimod), Ocrevus (ocrelizumab), Lemtrada (alemtuzumab), or Aubagio (teriflunomide)]

**AND**

**5** - Patient has not already received the FDA-recommended limit of 2 lifetime treatment courses (4 treatment cycles) of Mavenclad

|       |                                                                                                                                                                             |
|-------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Notes | <p>*Avonex, Rebif, Betaseron, Bafiertam, Kesimpta, Zeposia, and Extavia are non-preferred</p> <p>**Briumvi, Tyruko, Tysabri, Ocrevus, and Lemtrada are medical benefits</p> |
|-------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                        |                     |
|------------------------|---------------------|
| Product Name:Mavenclad |                     |
| Approval Length        | 2 month(s)          |
| Therapy Stage          | Reauthorization     |
| Guideline Type         | Prior Authorization |

### Approval Criteria

1 - Documentation of positive clinical response to Mavenclad treatment

**AND**

2 - Patient is NOT receiving Mavenclad in combination with another disease modifying therapy [e.g., interferon beta preparations, glatiramer acetate products, Tecfidera (dimethyl fumarate), Tysabri (natalizumab), Gilenya (fingolimod), Mayzent (siponimod), Ocrevus (ocrelizumab), Lemtrada (alemtuzumab), or Aubagio (teriflunomide)]

**AND**

3 - Patient has not already received the FDA-recommended limit of 2 lifetime treatment courses (4 treatment cycles) of Mavenclad

|       |                                                                                                                                              |
|-------|----------------------------------------------------------------------------------------------------------------------------------------------|
| Notes | Duration of coverage will be limited to 1 reauthorization to allow 2 cumulative treatment courses (4 treatment cycles) of Mavenclad therapy. |
|-------|----------------------------------------------------------------------------------------------------------------------------------------------|

## 2 . Revision History

| Date      | Notes                                                                                                                                           |
|-----------|-------------------------------------------------------------------------------------------------------------------------------------------------|
| 4/29/2025 | Added lifetime limit to initial criteria and revised statement in reauth.<br>Added Tyruko to list of alternatives and updated operational notes |

Mekinist



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-150996                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Guideline Name</b> | Mekinist                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 8/7/2024 |
|-----------------|----------|

## 1 . Criteria

|                       |                       |
|-----------------------|-----------------------|
| Product Name:Mekinist |                       |
| Diagnosis             | Melanoma              |
| Approval Length       | 12 month(s)           |
| Therapy Stage         | Initial Authorization |
| Guideline Type        | Prior Authorization   |

**Approval Criteria**

**1** - ONE of the following:

**1.1** BOTH of the following:

**1.1.1** ONE of the following:

**1.1.1.1** Unresectable melanoma

**OR**

**1.1.1.2** Metastatic melanoma

**OR**

**1.1.1.3** BOTH of the following:

**1.1.1.3.1** Prescribed as adjuvant therapy for melanoma involving the lymph node(s)

**AND**

**1.1.1.3.2** Used in combination with Tafenlar (dabrafenib)

**AND**

**1.1.2** Cancer is positive for BRAF V600 (gene) mutation

**OR**

**1.2** Distant metastatic uveal melanoma

**AND**

**2** - If the request is for Mekinist solution, there is a reason or special circumstance why the patient is unable to use Mekinist tablets (document reason or special circumstance)

|                               |                                    |
|-------------------------------|------------------------------------|
| <b>Product Name:</b> Mekinist |                                    |
| Diagnosis                     | Non-Small Cell Lung Cancer (NSCLC) |
| Approval Length               | 12 month(s)                        |
| Therapy Stage                 | Initial Authorization              |
| Guideline Type                | Prior Authorization                |

**Approval Criteria**

**1** - Diagnosis of non-small cell lung cancer (NSCLC)

**AND**

**2** - Disease is ONE of the following:

- Metastatic
- Advanced
- Recurrent

**AND**

**3** - Cancer is positive for BRAF V600E (gene) mutation

**AND**

**4** - Used in combination with Tafenlar (dabrafenib)

**AND**

**5** - If the request is for Mekinist solution, there is a reason or special circumstance why the patient is unable to use Mekinist tablets (document reason or special circumstance)

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                       |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Mekinist                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                       |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Thyroid Cancer        |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - ONE of the following:</p> <p>1.1 ALL of the following:</p> <p>1.1.1 Diagnosis of anaplastic thyroid cancer (ATC)</p> <p style="text-align: center;"><b>AND</b></p> <p>1.1.2 Cancer is positive for BRAF V600E (gene) mutation</p> <p style="text-align: center;"><b>AND</b></p> <p>1.1.3 Used in combination with Tafenlar (dabrafenib)</p> <p style="text-align: center;"><b>AND</b></p> <p>1.1.4 ONE of the following:</p> <p>1.1.4.1 Disease is ONE of the following:</p> <ul style="list-style-type: none"> <li>• Metastatic</li> <li>• Locally advanced</li> <li>• Unresectable</li> </ul> <p style="text-align: center;"><b>OR</b></p> |                       |

**1.1.4.2** Prescribed as adjuvant therapy following resection

**OR**

**1.2** ALL of the following:

**1.2.1** ONE of the following diagnoses:

- Follicular Carcinoma
- Oncocytic Carcinoma
- Papillary Carcinoma

**AND**

**1.2.2** ONE of the following:

- Unresectable locoregional recurrent disease
- Persistent disease
- Metastatic disease

**AND**

**1.2.3** ONE of the following:

- Patient has symptomatic disease
- Patient has progressive disease

**AND**

**1.2.4** Disease is refractory to radioactive iodine treatment

**AND**

**1.2.5** Cancer is positive for BRAF V600 mutation

**AND**

**1.2.6** Used in combination with Tafenlar (dabrafenib)

**AND**

**2** - If the request is for Mekinist solution, there is a reason or special circumstance why the patient is unable to use Mekinist tablets (document reason or special circumstance)

| Product Name:Mekinist                                                                                                                                                                                                                                                                                                           |                                      |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|
| Diagnosis                                                                                                                                                                                                                                                                                                                       | Central Nervous System (CNS) Cancers |
| Approval Length                                                                                                                                                                                                                                                                                                                 | 12 month(s)                          |
| Therapy Stage                                                                                                                                                                                                                                                                                                                   | Initial Authorization                |
| Guideline Type                                                                                                                                                                                                                                                                                                                  | Prior Authorization                  |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - ONE of the following:</p> <p><b>1.1</b> BOTH of the following:</p> <p><b>1.1.1</b> Patient has metastatic brain lesions</p> <p><b>AND</b></p> <p><b>1.1.2</b> Mekinist is active against the primary tumor (melanoma)</p> <p><b>OR</b></p> <p><b>1.2</b> Patient has a glioma</p> |                                      |



**AND**

**2** - Cancer is positive for BRAF V600E (gene) mutation

**AND**

**3** - Used in combination with Tafenlar (dabrafenib)

**AND**

**4** - If the request is for Mekinist solution, there is a reason or special circumstance why the patient is unable to use Mekinist tablets (document reason or special circumstance)

|                                                                                                                                                                                                                                                                                                                                                                           |                                                                           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------|
| Product Name:Mekinist                                                                                                                                                                                                                                                                                                                                                     |                                                                           |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                 | Epithelial Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer |
| Approval Length                                                                                                                                                                                                                                                                                                                                                           | 12 month(s)                                                               |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                             | Initial Authorization                                                     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                            | Prior Authorization                                                       |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of ONE of the following:</p> <ul style="list-style-type: none"> <li>• Epithelial Ovarian Cancer</li> <li>• Fallopian Tube Cancer</li> <li>• Primary Peritoneal Cancer</li> </ul> <p><b>AND</b></p> <p><b>2</b> - ONE of the following:</p> <ul style="list-style-type: none"> <li>• Persistent disease</li> </ul> |                                                                           |

- Recurrence in BRAF V600E positive tumors
- Recurrence of low-grade serous carcinoma

**AND**

**3** - If the request is for Mekinist solution, there is a reason or special circumstance why the patient is unable to use Mekinist tablets (document reason or special circumstance)

|                       |                       |
|-----------------------|-----------------------|
| Product Name:Mekinist |                       |
| Diagnosis             | Hepatobiliary Cancers |
| Approval Length       | 12 month(s)           |
| Therapy Stage         | Initial Authorization |
| Guideline Type        | Prior Authorization   |

**Approval Criteria**

**1** - Diagnosis of ONE of the following:

- Gallbladder cancer
- Extrahepatic Cholangiocarcinoma
- Intrahepatic Cholangiocarcinoma

**AND**

**2** - Used as subsequent treatment after progression on or after systemic treatment

**AND**

**3** - Disease is unresectable or metastatic

**AND**

**4** - Cancer is positive for BRAF V600E (gene) mutation

**AND**

**5** - Used in combination with Tafenlar (dabrafenib)

**AND**

**6** - If the request is for Mekinist solution, there is a reason or special circumstance why the patient is unable to use Mekinist tablets (document reason or special circumstance)

| Product Name:Mekinist                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                       |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Histiocytic Neoplasms |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of ONE of the following:</p> <ul style="list-style-type: none"> <li>• Langerhans Cell Histiocytosis</li> <li>• Erdheim-Chester Disease</li> <li>• Rosai-Dorfman Disease</li> </ul> <p><b>AND</b></p> <p><b>2</b> - ONE of the following:</p> <ul style="list-style-type: none"> <li>• Mitogen-activated protein (MAP) kinase pathway mutation</li> <li>• No detectable mutation</li> <li>• Testing not available</li> </ul> <p><b>AND</b></p> |                       |

**3** - If the request is for Mekinist solution, there is a reason or special circumstance why the patient is unable to use Mekinist tablets (document reason or special circumstance)

|                               |                       |
|-------------------------------|-----------------------|
| <b>Product Name:</b> Mekinist |                       |
| Diagnosis                     | Solid Tumors          |
| Approval Length               | 12 month(s)           |
| Therapy Stage                 | Initial Authorization |
| Guideline Type                | Prior Authorization   |

  

**Approval Criteria**

1 - Presence of solid tumor

**AND**

2 - Used as subsequent treatment after progression on or after systemic treatment

**AND**

3 - Disease is unresectable or metastatic

**AND**

4 - Cancer is positive for BRAF V600E (gene) mutation

**AND**

5 - Used in combination with Tafinlar (dabrafenib)

**AND**

**6** - If the request is for Mekinist solution, there is a reason or special circumstance why the patient is unable to use Mekinist tablets (document reason or special circumstance)

|                               |                                     |
|-------------------------------|-------------------------------------|
| <b>Product Name:</b> Mekinist |                                     |
| Diagnosis                     | Pancreatic Cancer, Ampullary Cancer |
| Approval Length               | 12 month(s)                         |
| Therapy Stage                 | Initial Authorization               |
| Guideline Type                | Prior Authorization                 |

**Approval Criteria**

**1** - Diagnosis of ONE of the following:

- Pancreatic adenocarcinoma
- Ampullary adenocarcinoma

**AND**

**2** - Disease is ONE of the following:

- Metastatic
- Locally advanced
- Unresectable

**AND**

**3** - Cancer is positive for BRAF V600E mutation

**AND**

**4** - Used in combination with Tafenlar (dabrafenib)

**AND**

**5** - If the request is for Mekinist solution, there is a reason or special circumstance why the patient is unable to use Mekinist tablets (document reason or special circumstance)

|                                                                                                                                                                                                                                                                                                                                                                                                                             |                       |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Mekinist                                                                                                                                                                                                                                                                                                                                                                                                       |                       |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                   | Hairy Cell Leukemia   |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                             | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                               | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                              | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of hairy cell leukemia</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Used in combination with Tafenlar (dabrafenib)</p> <p style="text-align: center;"><b>AND</b></p> <p>3 - If the request is for Mekinist solution, there is a reason or special circumstance why the patient is unable to use Mekinist tablets (document reason or special circumstance)</p> |                       |

|                                                                              |                       |
|------------------------------------------------------------------------------|-----------------------|
| Product Name:Mekinist                                                        |                       |
| Diagnosis                                                                    | Salivary Gland Tumor  |
| Approval Length                                                              | 12 month(s)           |
| Therapy Stage                                                                | Initial Authorization |
| Guideline Type                                                               | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of salivary gland tumor</p> |                       |

**AND**

**2** - Disease is one of the following:

- Recurrent and unresectable
- Metastatic

**AND**

**3** - Cancer is positive for BRAF V600E mutation

**AND**

**4** - Used in combination with Tafenlar (dabrafenib)

**AND**

**5** - If the request is for Mekinist solution, there is a reason or special circumstance why the patient is unable to use Mekinist tablets (document reason or special circumstance)

|                                                                                                                                           |                                       |
|-------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|
| Product Name:Mekinist                                                                                                                     |                                       |
| Diagnosis                                                                                                                                 | Gastrointestinal Stromal Tumor (GIST) |
| Approval Length                                                                                                                           | 12 month(s)                           |
| Therapy Stage                                                                                                                             | Initial Authorization                 |
| Guideline Type                                                                                                                            | Prior Authorization                   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of BRAF V600E-mutated gastrointestinal stromal tumor (GIST)</p> <p><b>AND</b></p> |                                       |

**2** - Disease is one of the following:

- Gross residual disease (R2 resection)
- Unresectable primary disease
- Tumor rupture
- Progressive
- Recurrent
- Metastatic

**AND**

**3** - Used in combination with Tafenlar (dabrafenib)

**AND**

**4** - If the request is for Mekinist solution, there is a reason or special circumstance why the patient is unable to use Mekinist tablets (document reason or special circumstance)

| Product Name:Mekinist                                                                                                  |                                                                                                                                                                                                                                                          |
|------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Diagnosis                                                                                                              | Melanoma, NSCLC, Thyroid Cancer, CNS Cancers, Epithelial Ovarian /Fallopian Tube /Primary Peritoneal Cancers, Hepatobiliary Cancers, Histiocytic Neoplasms, Solid Tumors, Pancreatic /Ampullary Cancer , Hairy Cell Leukemia, Salivary Gland Tumor, GIST |
| Approval Length                                                                                                        | 12 month(s)                                                                                                                                                                                                                                              |
| Therapy Stage                                                                                                          | Reauthorization                                                                                                                                                                                                                                          |
| Guideline Type                                                                                                         | Prior Authorization                                                                                                                                                                                                                                      |
| <b>Approval Criteria</b><br><b>1</b> - Patient does not show evidence of progressive disease while on Mekinist therapy |                                                                                                                                                                                                                                                          |

| Product Name:Mekinist |                          |
|-----------------------|--------------------------|
| Diagnosis             | NCCN Recommended Regimen |
| Approval Length       | 12 month(s)              |
| Therapy Stage         | Initial Authorization    |



| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                       | Prior Authorization |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - If the request is for Mekinist solution, there is a reason or special circumstance why the patient is unable to use Mekinist tablets (document reason or special circumstance)</p> |                     |

| Product Name:Mekinist                                                                                             |                          |
|-------------------------------------------------------------------------------------------------------------------|--------------------------|
| Diagnosis                                                                                                         | NCCN Recommended Regimen |
| Approval Length                                                                                                   | 12 month(s)              |
| Therapy Stage                                                                                                     | Reauthorization          |
| Guideline Type                                                                                                    | Prior Authorization      |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of positive clinical response to Mekinist therapy</p> |                          |

## 2 . Revision History

| Date     | Notes                                                                   |
|----------|-------------------------------------------------------------------------|
| 8/6/2024 | Added criteria for hairy cell leukemia, salivary gland tumor, and GIST. |

Mektovi



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-164675                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Guideline Name</b> | Mektovi                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 3/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                      |                       |
|----------------------|-----------------------|
| Product Name:Mektovi |                       |
| Diagnosis            | Melanoma              |
| Approval Length      | 12 month(s)           |
| Therapy Stage        | Initial Authorization |

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Prior Authorization |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1 - ALL of the following:</b></p> <p><b>1.1</b> Diagnosis of melanoma</p> <p style="text-align: center;"><b>AND</b></p> <p><b>1.2</b> Disease is one of the following:</p> <ul style="list-style-type: none"> <li>• Unresectable</li> <li>• Metastatic</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>1.3</b> Patient is positive for BRAFV600 mutation</p> <p style="text-align: center;"><b>AND</b></p> <p><b>1.4</b> Used in combination with Braftovi (encorafenib)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>1.5</b> ONE of the following:</p> <p><b>1.5.1</b> Patient has a contraindication or history of intolerance to ONE of the following regimens (please specify intolerance or contraindication):</p> <ul style="list-style-type: none"> <li>• Tafinlar (dabrafenib) plus Mekinist (trametinib)</li> <li>• Zelboraf (vemurafenib) plus Cotellic (cobimetinib)</li> </ul> <p style="text-align: center;"><b>OR</b></p> |                     |

**1.5.2** Provider attests that the patient is not an appropriate candidate based on the patient's clinical status or comorbidities for either of the following regimens:

- Tafinlar (dabrafenib) plus Mekinist (trametinib)
- Zelboraf (vemurafenib) plus Cotellic (cobimetinib)

**OR**

**1.5.3** For continuation of prior Mektovi therapy

**OR**

**2** - ALL of the following:

**2.1** Diagnosis of melanoma

**AND**

**2.2** Disease is one of the following:

- Unresectable
- Metastatic

**AND**

**2.3** Patient is positive for NRAS-mutation

**AND**

**2.4** Progression after prior immune checkpoint inhibitor therapy

|                      |                 |
|----------------------|-----------------|
| Product Name:Mektovi |                 |
| Diagnosis            | Melanoma        |
| Approval Length      | 12 month(s)     |
| Therapy Stage        | Reauthorization |

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Prior Authorization |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p>1 - Patient does not show evidence of progressive disease while on Mektovi therapy</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - ONE of the following:</p> <p>2.1 BOTH of the following:</p> <ul style="list-style-type: none"> <li>• BRAFV600 mutation positive</li> <li>• Used in combination with Braftovi (encorafenib)</li> </ul> <p style="text-align: center;"><b>OR</b></p> <p>2.2 NRAS-mutated tumor</p> |                     |

|                                                                                                                                                                                                                                                                                                                                                                          |                       |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Mektovi                                                                                                                                                                                                                                                                                                                                                     |                       |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                | Histiocytic Neoplasms |
| Approval Length                                                                                                                                                                                                                                                                                                                                                          | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                            | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                           | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of ONE of the following:</p> <ul style="list-style-type: none"> <li>• Multisystem Langerhans Cell Histiocytosis</li> <li>• Single-system lung Langerhans Cell Histiocytosis</li> <li>• Langerhans Cell Histiocytosis with CNS (central nervous system) lesions</li> </ul> <p style="text-align: center;"><b>AND</b></p> |                       |

**2 - ONE of the following:**

- Disease is positive for mitogen-activated protein (MAP) kinase pathway mutation
- No other detectable/actionable mutation
- Testing is not available

|                                                                                                                                                                                |                       |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Mektovi                                                                                                                                                           |                       |
| Diagnosis                                                                                                                                                                      | Serous Carcinoma      |
| Approval Length                                                                                                                                                                | 12 month(s)           |
| Therapy Stage                                                                                                                                                                  | Initial Authorization |
| Guideline Type                                                                                                                                                                 | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1 - Diagnosis of low-grade serous carcinoma</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>2 - Disease is recurrent</b></p> |                       |

|                                                                                                                                  |                                         |
|----------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|
| Product Name:Mektovi                                                                                                             |                                         |
| Diagnosis                                                                                                                        | Histiocytic Neoplasms, Serous Carcinoma |
| Approval Length                                                                                                                  | 12 month(s)                             |
| Therapy Stage                                                                                                                    | Reauthorization                         |
| Guideline Type                                                                                                                   | Prior Authorization                     |
| <p><b>Approval Criteria</b></p> <p><b>1 - Patient does not show evidence of progressive disease while on Mektovi therapy</b></p> |                                         |

|                      |
|----------------------|
| Product Name:Mektovi |
|----------------------|

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                       |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Gastrointestinal Stromal Tumor (GIST) |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 12 month(s)                           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Initial Authorization                 |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Prior Authorization                   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of succinate dehydrogenase (SDH)-deficient gastrointestinal stromal tumor (GIST)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Disease is ONE of the following:</p> <ul style="list-style-type: none"> <li>• Gross residual disease (R2 resection)</li> <li>• Unresectable primary disease</li> <li>• Tumor rupture</li> <li>• Progressive</li> <li>• Recurrent</li> <li>• Metastatic</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Used in combination with imatinib mesylate (generic Gleevec)</p> |                                       |

|                                                                                                                                  |                                       |
|----------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|
| Product Name:Mektovi                                                                                                             |                                       |
| Diagnosis                                                                                                                        | Gastrointestinal Stromal Tumor (GIST) |
| Approval Length                                                                                                                  | 12 month(s)                           |
| Therapy Stage                                                                                                                    | Reauthorization                       |
| Guideline Type                                                                                                                   | Prior Authorization                   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Patient does not show evidence of progressive disease while on Mektovi therapy</p> |                                       |

**AND**

**2** - Used in combination with imatinib mesylate (Gleevec)

Product Name:Mektovi

|           |                                    |
|-----------|------------------------------------|
| Diagnosis | Non-Small Cell Lung Cancer (NSCLC) |
|-----------|------------------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

### Approval Criteria

**1** - Diagnosis of non-small cell lung cancer (NSCLC)

**AND**

**2** - Disease is one of the following:

- Recurrent
- Advanced
- Metastatic

**AND**

**3** - Patient is positive for BRAFV600 mutation

**AND**

**4** - Used in combination with Braftovi (encorafenib)

**AND**



**5 - ONE of the following:**

**5.1** Patient has a contraindication or history of intolerance to Tafenlar (dabrafenib) plus Mekinist (trametinib) (please specify intolerance or contraindication)

**OR**

**5.2** Provider attests that the patient is not an appropriate candidate based on the patient's clinical status or comorbidities for Tafenlar (dabrafenib) plus Mekinist (trametinib)

**OR**

**5.3** For continuation of prior Mektovi therapy

|                                                                                                                                                                                                                      |                                    |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|
| Product Name:Mektovi                                                                                                                                                                                                 |                                    |
| Diagnosis                                                                                                                                                                                                            | Non-Small Cell Lung Cancer (NSCLC) |
| Approval Length                                                                                                                                                                                                      | 12 month(s)                        |
| Therapy Stage                                                                                                                                                                                                        | Reauthorization                    |
| Guideline Type                                                                                                                                                                                                       | Prior Authorization                |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Patient does not show evidence of progressive disease while on Mektovi therapy</p> <p><b>AND</b></p> <p><b>2</b> - Used in combination with Braftovi (encorafenib)</p> |                                    |

|                      |                          |
|----------------------|--------------------------|
| Product Name:Mektovi |                          |
| Diagnosis            | NCCN Recommended Regimen |
| Approval Length      | 12 month(s)              |
| Therapy Stage        | Initial Authorization    |

|                                                                                                                                                |                     |
|------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Guideline Type                                                                                                                                 | Prior Authorization |
| <b>Approval Criteria</b><br><br><b>1</b> - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium |                     |

|                                                                                                           |                          |
|-----------------------------------------------------------------------------------------------------------|--------------------------|
| Product Name:Mektovi                                                                                      |                          |
| Diagnosis                                                                                                 | NCCN Recommended Regimen |
| Approval Length                                                                                           | 12 month(s)              |
| Therapy Stage                                                                                             | Reauthorization          |
| Guideline Type                                                                                            | Prior Authorization      |
| <b>Approval Criteria</b><br><br><b>1</b> - Documentation of positive clinical response to Mektovi therapy |                          |

## 2 . Revision History

| Date     | Notes                                        |
|----------|----------------------------------------------|
| 2/4/2025 | Updated formularies. Updated reauth criteria |

Mepron



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-127422                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Guideline Name</b> | Mepron                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 8/1/2023 |
|-----------------|----------|

## 1 . Criteria

|                                                |                                                    |
|------------------------------------------------|----------------------------------------------------|
| Product Name: Brand Mepron, generic atovaquone |                                                    |
| Diagnosis                                      | Pneumocystis Jirovecii Pneumonia (PCP) Prophylaxis |
| Approval Length                                | 12 month(s)                                        |
| Guideline Type                                 | Prior Authorization                                |

### Approval Criteria

**1** - The patient has a diagnosis [e.g., HIV (human immunodeficiency virus)] warranting PCP (pneumocystis jirovecii pneumonia) infection prophylaxis

**AND**

**2** - The patient has a documented intolerance or contraindication to trimethoprim-sulfamethoxazole (TMP-SMX) and dapsone (please specify intolerance or contraindication)

Product Name: Brand Mepron, generic atovaquone

|           |                                                  |
|-----------|--------------------------------------------------|
| Diagnosis | Pneumocystis Jirovecii Pneumonia (PCP) Treatment |
|-----------|--------------------------------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

### Approval Criteria

**1** - The patient has a diagnosis of mild to moderate pneumonia caused by pneumocystis jirovecii

**AND**

**2** - ONE of the following:

**2.1** Failure of trimethoprim-sulfamethoxazole (TMP-SMX) confirmed by claims history or submitted medical records

**OR**

**2.2** History of intolerance or contraindication to TMP-SMX (please specify intolerance or contraindication)

## 2 . Revision History

| Date      | Notes                |
|-----------|----------------------|
| 6/30/2023 | Updated formularies. |

Methadose 40mg



## Prior Authorization Guideline

|                       |                                                                                                         |
|-----------------------|---------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-60331                                                                                                |
| <b>Guideline Name</b> | Methadose 40mg                                                                                          |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>Medicaid - Community &amp; State New Jersey (PSI2300)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 3/1/2020 |
|-----------------|----------|

## 1 . Criteria

|                                                                                                                                                                                      |                     |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Methadose, Methadone *                                                                                                                                                  |                     |
| Diagnosis                                                                                                                                                                            | Opioid Use Disorder |
| Approval Length                                                                                                                                                                      | 12 month(s)         |
| Guideline Type                                                                                                                                                                       | Prior Authorization |
| <b>Approval Criteria</b><br><br>1 - The patient has a Diagnostic and Statistical Manual of Mental Disorders, 4th Edition, Text Revision (DSM-IV-TR) diagnosis of opioid use disorder |                     |

**AND**

**2** - The requested quantity does not exceed 120 milligrams daily

|       |                                          |
|-------|------------------------------------------|
| Notes | *Up to 120 mg per day will be authorized |
|-------|------------------------------------------|

Product Name:Methadose, Methadone \*

|           |                     |
|-----------|---------------------|
| Diagnosis | Opioid Use Disorder |
|-----------|---------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|                |                |
|----------------|----------------|
| Guideline Type | Quantity Limit |
|----------------|----------------|

### Approval Criteria

**1** - Physician has provided rationale for the need to exceed the daily limit

|       |                                                  |
|-------|--------------------------------------------------|
| Notes | *Up to the requested quantity will be authorized |
|-------|--------------------------------------------------|

## 2 . Revision History

| Date | Notes |
|------|-------|
|------|-------|

|           |                    |
|-----------|--------------------|
| 1/24/2020 | C&S Implementation |
|-----------|--------------------|

Migranal, Trudhesa



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-192189                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Guideline Name</b> | Migranal, Trudhesa                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 4/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                                                                                        |                     |
|----------------------------------------------------------------------------------------|---------------------|
| Product Name: Brand Migranal, generic dihydroergotamine mesylate nasal spray, Trudhesa |                     |
| Approval Length                                                                        | 12 month(s)         |
| Guideline Type                                                                         | Prior Authorization |
| Approval Criteria                                                                      |                     |



**1** - Diagnosis of migraine headaches with or without aura

**AND**

**2** - ONE of the following:

**2.1** Failure to THREE preferred 5-HT<sub>1</sub> receptor agonist (triptan) alternatives (e.g., sumatriptan, rizatriptan, or naratriptan), one of which must be sumatriptan nasal spray, confirmed by claims history or submission of medical records

**OR**

**2.2** History of contraindication or intolerance to THREE preferred 5-HT<sub>1</sub> receptor agonist (triptan) alternatives (e.g., sumatriptan, rizatriptan, or naratriptan), one of which must be sumatriptan nasal spray (please specify intolerance or contraindication)

Product Name: Brand Migranal, generic dihydroergotamine mesylate nasal spray, Trudhesa

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|                |                |
|----------------|----------------|
| Guideline Type | Quantity Limit |
|----------------|----------------|

**Approval Criteria**

**1** - Diagnosis of migraine headaches with or without aura

**AND**

**2** - Prescribed by, or in consultation with, ONE of the following:

- Neurologist
- Pain management specialist

**AND**

**3** - Currently receiving prophylactic therapy with at least ONE of the following:

- A beta-blocker (i.e., atenolol, metoprolol, nadolol, propranolol, or timolol\*)
- Candesartan (generic Atacand)\*
- A calcitonin gene-related peptide receptor\*\*\* (CGRP) antagonist or inhibitor for preventive treatment of migraine [i.e., Aimovig (erenumab), Ajovy\* (fremanezumab), Emgality (galcanezumab), Qulipta\* (atogepant), Vyepti\*\* (eptinezumab-jjmr)]
- Divalproex sodium (Depakote/Depakote ER)
- OnabotulinumtoxinA (Botox)\*\*
- A serotonin-norepinephrine reuptake inhibitor [i.e., duloxetine (Cymbalta), venlafaxine (Effexor/Effexor XR)]
- Topiramate (Topamax)
- A tricyclic antidepressant [i.e., amitriptyline (Elavil), nortriptyline (Pamelor)]

**AND**

**4 - BOTH of the following:**

**4.1 ONE of the following:**

**4.1.1** Higher dose or quantity is supported by the manufacturer's prescribing information

**OR**

**4.1.2** Higher dose or quantity is supported by ONE of the following compendia:

- American Hospital Formulary Service Drug Information
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopoeia-National Formulary (USP-NF)

**OR**

**4.1.3** Physician provides evidence from published biomedical literature to support safety and additional efficacy at doses/quantities greater than those approved by the Food and Drug Administration (FDA) for the diagnosis indicated

**AND**

**4.2** Physician acknowledges that the potential benefit outweighs the risk associated with the higher dose or quantity

|       |                                                                                                                                                                                                                 |
|-------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Notes | <p>*This is non-preferred and should not be included in denial to provider .</p> <p>**This is a medical benefit and should not be included in denial to provider.</p> <p>***Requires a prior authorization.</p> |
|-------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

## 2 . Revision History

| Date      | Notes                                                                                                                      |
|-----------|----------------------------------------------------------------------------------------------------------------------------|
| 2/24/2025 | Updated formularies. Updated step therapy language, naratriptan step therapy removed. Updated list of prophylactic therapy |

Miplyffa



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-459189                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Guideline Name</b> | Miplyffa                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Pennsylvania (ACUPA)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 12/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                       |                       |
|-----------------------|-----------------------|
| Product Name:Miplyffa |                       |
| Approval Length       | 12 month(s)           |
| Therapy Stage         | Initial Authorization |

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Prior Authorization |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of Niemann-Pick disease type C (NPC)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Diagnosis has been genetically confirmed by mutation analysis of NPC1 and NPC2 genes</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Miplyffa is being used to treat neurological manifestations of NPC</p> <p style="text-align: center;"><b>AND</b></p> <p><b>4</b> - Miplyffa is prescribed in combination with miglustat</p> <p style="text-align: center;"><b>AND</b></p> <p><b>5</b> - Patient is NOT receiving Miplyffa in combination with Aqneursa (levacetylleucine)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>6</b> - Miplyffa is prescribed by or in consultation with a provider with expertise in the treatment of NPC</p> |                     |

|                       |                     |
|-----------------------|---------------------|
| Product Name:Miplyffa |                     |
| Approval Length       | 12 month(s)         |
| Therapy Stage         | Reauthorization     |
| Guideline Type        | Prior Authorization |

### Approval Criteria

**1** - Documentation of positive clinical response to Miplyffa therapy (e.g., slowed disease progression from baseline based on assessment with NPC–specific scales)

**AND**

**2** - Miplyffa continues to be prescribed in combination with miglustat

**AND**

**3** - Patient is NOT receiving Miplyffa in combination with Aqneursa (levacetylleucine)

**AND**

**4** - Miplyffa is prescribed by or in consultation with a provider with expertise in the treatment of NPC

## 2 . Revision History

| Date       | Notes                                                                                             |
|------------|---------------------------------------------------------------------------------------------------|
| 11/19/2025 | Removed ACUMI from markets in scope. Rearranged formulary order. No changes to clinical criteria. |

Mozobil



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|-----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-231197                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Guideline Name</b> | Mozobil                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania (ACUPA)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Washington (ACUWA, ACUWAAHE, ACUWAC)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 5/1/2025 |
|-----------------|----------|

## 1 . Criteria

Product Name: Brand Mozobil, generic plerixafor

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                      |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Hematopoietic Stem Cell Mobilization |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 30 Day(s)                            |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Prior Authorization                  |
| <p><b>Approval Criteria</b></p> <p><b>1 - ONE of the following:</b></p> <ul style="list-style-type: none"> <li>Patients with non-Hodgkin's lymphoma (NHL) who will be undergoing autologous hematopoietic stem cell (HSC) transplantation</li> <li>Patients with multiple myeloma (MM) who will be undergoing autologous HSC transplantation</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>2 - Used in combination with granulocyte-colony stimulating factor (G-CSF) [e.g., Zarxio (filgrastim)]</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>3 - Prescribed by or in consultation with a hematologist/oncologist</b></p> |                                      |

|                                                                                                                                                       |                           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name: Brand Mozobil, generic plerixafor                                                                                                       |                           |
| Diagnosis                                                                                                                                             | NCCN Recommended Regimens |
| Approval Length                                                                                                                                       | 12 month(s)               |
| Therapy Stage                                                                                                                                         | Initial Authorization     |
| Guideline Type                                                                                                                                        | Prior Authorization       |
| <p><b>Approval Criteria</b></p> <p><b>1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium</b></p> |                           |



|                                                                                                          |                           |
|----------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name: Brand Mozobil, generic plerixafor                                                          |                           |
| Diagnosis                                                                                                | NCCN Recommended Regimens |
| Approval Length                                                                                          | 12 month(s)               |
| Therapy Stage                                                                                            | Reauthorization           |
| Guideline Type                                                                                           | Prior Authorization       |
| <b>Approval Criteria</b><br><br>1 - Documentation of positive clinical response to the requested therapy |                           |

## 2 . Revision History

| Date      | Notes                                                 |
|-----------|-------------------------------------------------------|
| 3/27/2025 | Combined formularies. No change to clinical criteria. |

MS Agents



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-331199                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Guideline Name</b> | MS Agents                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 8/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                                                             |                     |
|-------------------------------------------------------------|---------------------|
| Product Name:generic glatiramer, Glatopa, Mayzent, Plegridy |                     |
| Approval Length                                             | 12 month(s)         |
| Guideline Type                                              | Prior Authorization |
| Approval Criteria                                           |                     |

**1 - Diagnosis of multiple sclerosis (MS)**

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                          |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------|
| Product Name:Avonex, Bafiertam, Betaseron, Extavia, Kesimpta, Ponvory, Rebif, Vumerity                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                          |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 12 month(s)                              |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Initial Authorization                    |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Prior Authorization                      |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of multiple sclerosis (MS)</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - If the request is non-preferred*, ONE of the following:</p> <ul style="list-style-type: none"> <li>• Failure of at least TWO of the preferred alternatives (one of which must be a preferred dimethyl fumarate product) confirmed by claims history or submitted medical records</li> <li>• History of intolerance or contraindication to ALL of the preferred alternatives (please specify intolerance or contraindication)</li> <li>• Patient is currently on the requested drug therapy as confirmed by claims history or submission of medical records</li> </ul> |                                          |
| Notes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | *See table 1 in background for PDL links |

|                                                                                 |                       |
|---------------------------------------------------------------------------------|-----------------------|
| Product Name:Tascenso ODT                                                       |                       |
| Approval Length                                                                 | 12 month(s)           |
| Therapy Stage                                                                   | Initial Authorization |
| Guideline Type                                                                  | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of multiple sclerosis (MS)</p> |                       |

**AND**

**2** - Patient is 10 years of age or older

**AND**

**3** - ONE of the following:

- Failure of fingolimod 0.5mg (generic Gilenya 0.5 mg) confirmed by claims history or submitted medical records
- History of intolerance or contraindication to fingolimod 0.5mg (generic Gilenya 0.5 mg) (please specify intolerance or contraindication)
- Patient is currently on Tascenso ODT therapy as confirmed by claims history or submission of medical records

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                       |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name: Brand Aubagio, Brand Copaxone, Brand Gilenya 0.5mg, Brand Tecfidera                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                       |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of multiple sclerosis (MS)</p> <p><b>AND</b></p> <p><b>2</b> - If the request is non-preferred*, ONE of the following:</p> <ul style="list-style-type: none"> <li>• Failure of at least two of the preferred alternatives (one of which must be a preferred dimethyl fumarate product) confirmed by claims history or submitted medical records</li> <li>• History of intolerance or contraindication to all of the preferred alternatives (please specify intolerance or contraindication)</li> <li>• Patient is currently on the requested drug therapy as confirmed by claims history or submission of medical records</li> </ul> |                       |

**AND****3 - ONE of the following:**

- The brand is being requested because of an adverse reaction, allergy or sensitivity to a generic/authorized generic equivalent (specify the adverse reaction, allergy, or sensitivity)
- The brand is being requested due to an incomplete response with a generic/authorized generic equivalent, as documented by submission of medical records
- The brand is being requested because transition to a generic/authorized generic equivalent could result in destabilization of the patient.
- Special clinical circumstances exist that preclude the use of a generic/authorized generic equivalent of the brand medication for the patient (document special clinical circumstances)

Notes

\*See table 1 in background for PDL links

Product Name: Avonex, Bafiertam, Betaseron, Extavia, Kesimpta, Ponvory, Rebif, Vumerity, Tascenso ODT, Brand Aubagio, Brand Copaxone, Brand Gilenya 0.5 mg, Brand Tecfidera

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                 |
|---------------|-----------------|
| Therapy Stage | Reauthorization |
|---------------|-----------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

1 - Documentation of positive clinical response to therapy

**2 . Background****Benefit/Coverage/Program Information****Table 1: PDL Links**

- **CO:** <https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html>

- **HI:** <https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html>
- **MD:** <https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-cp-pharmacy.html>
- **NJ:** <https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html>
- **NY/NY EPP:** <https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html>
- **PA CHIP:** <https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP>
- **RI:** <https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html>
- **NM:** <https://www.uhcprovider.com/en/health-plans-by-state/new-mexico-health-plans/nm-comm-plan-home/nm-cp-pharmacy.html>

### 3 . Revision History

| Date      | Notes                                                                        |
|-----------|------------------------------------------------------------------------------|
| 7/15/2025 | Updated formularies. Updated nonpreferred language. Minor formatting changes |

Mulpleta



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-135118                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Guideline Name</b> | Mulpleta                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>•</li> <li>•</li> <li>•</li> <li>•</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 1/1/2024 |
|-----------------|----------|

## 1 . Criteria

|                       |                     |
|-----------------------|---------------------|
| Product Name:Mulpleta |                     |
| Diagnosis             | Thrombocytopenia    |
| Approval Length       | 1 month(s)          |
| Guideline Type        | Prior Authorization |

**Approval Criteria**

1 - Diagnosis of thrombocytopenia

**AND**

2 - Patient has chronic liver disease

**AND**

3 - Patient is scheduled to undergo a procedure

**2 . Revision History**

| Date       | Notes                |
|------------|----------------------|
| 10/17/2023 | Updated formularies. |



Multaq



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-135119                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Guideline Name</b> | Multaq                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>•</li> <li>•</li> <li>•</li> <li>•</li> <li>•</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 1/1/2024 |
|-----------------|----------|

## 1 . Criteria

|                     |                     |
|---------------------|---------------------|
| Product Name:Multaq |                     |
| Approval Length     | 12 month(s)         |
| Guideline Type      | Prior Authorization |

### Approval Criteria

**1** - ALL of the following:

**1.1** Diagnosis of ONE of the following:

- Paroxysmal Atrial Fibrillation (AF)
- Persistent AF defined as AF less than 6 months duration

**AND**

**1.2** ONE of the following:

- Patient is in sinus rhythm
- Patient is planned to undergo cardioversion to sinus rhythm

**AND**

**1.3** Patient does NOT have New York Heart Association (NYHA) Class IV heart failure

**AND**

**1.4** Patient does NOT have symptomatic heart failure with recent decompensation requiring hospitalization

**OR**

**2** - For continuation of current therapy

## 2 . Revision History

| Date       | Notes                                     |
|------------|-------------------------------------------|
| 10/18/2023 | Updated formularies, cleaned up criteria. |



Myalept



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-371232                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Guideline Name</b> | Myalept                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State Pennsylvania (ACUPA)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 9/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                       |             |
|-----------------------|-------------|
| Product Name: Myalept |             |
| Approval Length       | 12 month(s) |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                       |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of congenital or acquired generalized lipodystrophy associated with leptin deficiency</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Used as an adjunct to diet modification</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Prescribed by an endocrinologist</p> <p style="text-align: center;"><b>AND</b></p> <p><b>4</b> - Patient has at least ONE of the following:</p> <p><b>4.1</b> Diabetes mellitus or insulin resistance with persistent hyperglycemia (hemoglobin A1C greater than 7.0%) despite BOTH of the following:</p> <ul style="list-style-type: none"> <li>• Dietary intervention</li> <li>• Optimized insulin therapy at maximum tolerated doses</li> </ul> <p style="text-align: center;"><b>OR</b></p> <p><b>4.2</b> Persistent hypertriglyceridemia (triglycerides greater than 200 milligrams per deciliter) despite BOTH of the following:</p> <ul style="list-style-type: none"> <li>• Dietary intervention</li> <li>• Optimized therapy with at least two triglyceride-lowering agents from different classes (e.g., fibrates, statins) at maximum tolerated doses</li> </ul> |                       |

|                                                                                                                                                                                                                                                                                                      |                     |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name: Myalept                                                                                                                                                                                                                                                                                |                     |
| Approval Length                                                                                                                                                                                                                                                                                      | 12 month(s)         |
| Therapy Stage                                                                                                                                                                                                                                                                                        | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                                                                       | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p>1 - Documentation of positive clinical response to Myalept therapy</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Used as an adjunct to diet modification</p> <p style="text-align: center;"><b>AND</b></p> <p>3 - Prescribed by an endocrinologist</p> |                     |

## 2 . Revision History

| Date      | Notes              |
|-----------|--------------------|
| 8/18/2025 | Added NM formulary |

Mycapssa



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-192203                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Guideline Name</b> | Mycapssa                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 4/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                       |             |
|-----------------------|-------------|
| Product Name:Mycapssa |             |
| Diagnosis             | Acromegaly  |
| Approval Length       | 12 month(s) |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                       |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1 - ALL of the following:</b></p> <p><b>1.1</b> Diagnosis of acromegaly by ONE of the following:</p> <ul style="list-style-type: none"> <li>Serum GH (growth hormone) level &gt; 1 ng/mL (nanogram/milliliter) after a 2-hour oral glucose tolerance test (OGTT) at time of diagnosis</li> <li>Elevated serum IGF-1 (insulin-like growth factor-1) levels (above the age and gender adjusted normal range as provided by the physician's lab) at time of diagnosis</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>1.2</b> ONE of the following:</p> <p><b>1.2.1</b> Inadequate response to ONE of the following:</p> <ul style="list-style-type: none"> <li>Surgical resection</li> <li>Pituitary irradiation</li> <li>Dopamine agonist (e.g., bromocriptine, cabergoline) therapy</li> </ul> <p style="text-align: center;"><b>OR</b></p> <p><b>1.2.2</b> Not a candidate for ALL of the following:</p> <ul style="list-style-type: none"> <li>Surgical resection</li> <li>Pituitary irradiation</li> <li>Dopamine agonist (e.g., bromocriptine, cabergoline) therapy</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>1.3</b> Patient has responded to and tolerated treatment with ONE of the following somatostatin analogs:</p> <ul style="list-style-type: none"> <li>Sandostatin (octreotide) or Sandostatin LAR</li> </ul> |                       |



- Somatuline Depot (lanreotide) [Note: Somatuline Depot (lanreotide) might not be covered on your pharmacy prescription drug benefit. Coverage might be available on your medical benefit.]

**AND**

**1.4** The provider has submitted clinical justification why the patient is unable to be maintained on current octreotide or lanreotide therapy\*

**OR**

**2** - Patient is currently on Mycapssa therapy for acromegaly

|       |                                                                                                                                        |
|-------|----------------------------------------------------------------------------------------------------------------------------------------|
| Notes | *UHC generally does not consider frequency of dosing and/or lack of compliance to dosing regimens, an indication of medical necessity. |
|-------|----------------------------------------------------------------------------------------------------------------------------------------|

|                                                                                                              |                     |
|--------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Mycapssa                                                                                        |                     |
| Diagnosis                                                                                                    | Acromegaly          |
| Approval Length                                                                                              | 12 month(s)         |
| Therapy Stage                                                                                                | Reauthorization     |
| Guideline Type                                                                                               | Prior Authorization |
| <b>Approval Criteria</b><br><br><b>1</b> - Documentation of a positive clinical response to Mycapssa therapy |                     |

## 2 . Revision History

| Date      | Notes                                                      |
|-----------|------------------------------------------------------------|
| 2/25/2025 | Updated formularies. Updated initial auth criteria wording |

Mytesi



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-228221                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Guideline Name</b> | Mytesi                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania (ACUPA)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 5/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                     |                     |
|---------------------|---------------------|
| Product Name:Mytesi |                     |
| Approval Length     | 12 month(s)         |
| Guideline Type      | Prior Authorization |

**Approval Criteria**

1 - Diagnosis of human immunodeficiency virus (HIV)/acquired immunodeficiency syndrome (AIDS) associated diarrhea

**2 . Revision History**

| Date      | Notes                                                  |
|-----------|--------------------------------------------------------|
| 3/27/2025 | Combined formularies. No changes to clinical criteria. |

Nasonex, Xhance



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-155771                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Guideline Name</b> | Nasonex, Xhance                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 10/1/2024 |
|-----------------|-----------|

## 1 . Criteria

|                                                                                        |                     |
|----------------------------------------------------------------------------------------|---------------------|
| Product Name: Brand Nasonex, generic mometasone (Rx version only), Allergy nasal spray |                     |
| Approval Length                                                                        | 12 month(s)         |
| Guideline Type                                                                         | Prior Authorization |
| Approval Criteria                                                                      |                     |

**1** - Failure to ONE of the following as confirmed by claims history or submission of medical record

- Prescription fluticasone nasal spray (generic Flonase)
- Flonase allergy relief (fluticasone propionate) OTC brand or generic

**OR**

**2** - History of contraindication or intolerance to BOTH of the following (please specify contraindication or intolerance)

- Prescription fluticasone nasal spray (generic Flonase)
- Flonase allergy relief (fluticasone propionate) OTC brand or generic

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                     |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Xhance                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                     |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 12 month(s)         |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - One of the following:</p> <p><b>1.1</b> Diagnosis of chronic rhinosinusitis with nasal polyps</p> <p><b>OR</b></p> <p><b>1.2</b> Diagnosis of chronic rhinosinusitis without nasal polyps</p> <p><b>AND</b></p> <p><b>2</b> - One of the following:</p> <p><b>2.1</b> Failure to BOTH of the following as confirmed by claims history or submission of medical records</p> <ul style="list-style-type: none"> <li>• Fluticasone nasal spray (generic Flonase, Flonase Allergy)</li> </ul> |                     |

- Mometasone nasal spray (generic Nasonex or Nasonex 24H Allergy)

**OR**

**2.2** History of contraindication or intolerance to BOTH of the following (please specify contraindication or intolerance)

- Fluticasone nasal spray (generic Flonase, Flonase Allergy)
- Mometasone nasal spray (generic Nasonex or Nasonex 24H Allergy)

## 2 . Revision History

| Date      | Notes |
|-----------|-------|
| 9/24/2024 | New.  |

Nayzilam and Valtoco



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-242259                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Guideline Name</b> | Nayzilam and Valtoco                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 7/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                       |                       |
|-----------------------|-----------------------|
| Product Name:Nayzilam |                       |
| Approval Length       | 12 month(s)           |
| Therapy Stage         | Initial Authorization |
| Guideline Type        | Prior Authorization   |

**Approval Criteria**

1 - Diagnosis of epilepsy

**AND**

2 - Nayzilam is being prescribed for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity that are distinct from a patient's usual seizure pattern

**AND**

3 - Prescriber has given a clinical reason or special circumstance why the patient is unable to use diazepam rectal gel (please document reason/special circumstance)

Product Name:Nayzilam

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                 |
|---------------|-----------------|
| Therapy Stage | Reauthorization |
|---------------|-----------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

1 - Documentation of positive clinical response to therapy

Product Name:Valtoco

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**



**1 - Diagnosis of epilepsy**

**AND**

**2 - Valtoco is being prescribed for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity that are distinct from a patient's usual seizure pattern**

**AND**

**3 - Prescriber has given a clinical reason or special circumstance why the patient is unable to use diazepam rectal gel (please document reason/special circumstance)**

**AND**

**4 - ONE of the following:**

**4.1 Patient is less than 12 years of age**

**OR**

**4.2 ONE of the following:**

**4.2.1 Failure of Nayzilam confirmed by claims history or submitted medical records**

**OR**

**4.2.2 History of contraindication or intolerance to Nayzilam (please specify contraindication or intolerance)**

|                      |                     |
|----------------------|---------------------|
| Product Name:Valtoco |                     |
| Approval Length      | 12 month(s)         |
| Therapy Stage        | Reauthorization     |
| Guideline Type       | Prior Authorization |

**Approval Criteria**

1 - Documentation of positive clinical response to therapy

**2 . Revision History**

| Date      | Notes                                                                                              |
|-----------|----------------------------------------------------------------------------------------------------|
| 4/23/2025 | Combined formularies. Updated language for criterion pertaining to diazepam gel, where applicable. |

Nemluvio



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-375188                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Guideline Name</b> | Nemluvio                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 9/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                       |                       |
|-----------------------|-----------------------|
| Product Name:Nemluvio |                       |
| Diagnosis             | Atopic Dermatitis     |
| Approval Length       | 12 month(s)           |
| Therapy Stage         | Initial Authorization |
| Guideline Type        | Prior Authorization   |

## **Approval Criteria**

**1** - Diagnosis of moderate-to-severe chronic atopic dermatitis

**AND**

**2** - One of the following:

**2.1** Inadequate response to TWO of the following therapeutic classes of topical therapies as confirmed by claims history or submission of medical records:

- One medium, high or very-high potency topical corticosteroid [e.g., mometasone furoate (generic Elocon), fluocinolone acetonide (generic Synalar), fluocinonide (generic Lidex)]\*
- One topical calcineurin inhibitor [e.g., pimecrolimus (generic Elidel), tacrolimus (generic Protopic)]
- Eucrisa (crisaborole)

**OR**

**2.2** History of contraindication or intolerance to ALL of the following therapeutic classes of topical therapies (please specify contraindication or intolerance):

- One medium, high very-high potency topical corticosteroid [e.g., mometasone furoate (generic Elocon), fluocinolone acetonide (generic Synalar), fluocinonide (generic Lidex)]\*
- One topical calcineurin inhibitor [e.g., pimecrolimus (generic Elidel), tacrolimus (generic Protopic)]
- Eucrisa (crisaborole)

**OR**

**2.3** Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of atopic dermatitis as documented by claims history or submission of medical records [e.g., Adbry (tralokinumab-ldrm), Cibinqo (abrocitinib), Dupixent (dupilumab), Ebglyss (lebrikizumab-lbkz), Opzelura (ruxolitinib), Rinvoq (upadacitinib)]

**AND**

**3 - One of the following:**

**3.1** Failure to BOTH of the following as confirmed by claims history or submission of medical records:

- Adbry (tralokinumab-ldrm)
- Dupixent (dupilumab)

**OR**

**3.2** History of contraindication or intolerance to BOTH of the following (please specify contraindication or intolerance):

- Adbry (tralokinumab-ldrm)
- Dupixent (dupilumab)

**OR**

**3.3** Patient is currently on Nemluvio therapy as confirmed by claims history or submission of medical records

**AND**

**4 -** Nemluvio will be used in combination with a topical corticosteroid and/or topical calcineurin inhibitor

**AND**

**5 -** Patient is not receiving Nemluvio in combination with either of the following for treatment of the same indication:

- Biologic immunomodulator [e.g., Adbry (tralokinumab-ldrm), Dupixent (dupilumab), Ebglyss (lebrikizumab-lbkz)]
- Janus kinase inhibitor [e.g., Cibinqo (abrocitinib), Opzelura (topical ruxolitinib), Rinvoq (upadacitinib), Xeljanz/XR (tofacitinib)]

**AND**

**6** - Prescribed by or in consultation with one of the following:

- Dermatologist
- Allergist
- Immunologist

Notes

\*See Table 1 for relative potencies of topical corticosteroids.

Product Name:Nemluvio

Diagnosis Atopic Dermatitis

Therapy Stage Reauthorization

Guideline Type Prior Authorization

### Approval Criteria

**1** - Documentation of positive clinical response to Nemluvio therapy

**AND**

**2** - Patient is not receiving Nemluvio in combination with either of the following for the treatment of the same indication:

- Biologic immunomodulator [e.g., Adbry (tralokinumab-ldrm), Dupixent (dupilumab), Ebglyss (lebrikizumab-lbkz)]
- Janus kinase inhibitor [e.g., Cibinqo (abrocitinib), Opzelura (topical ruxolitinib), Rinvoq (upadacitinib), Xeljanz/XR (tofacitinib)]

**AND**

**3** - Prescribed by or in consultation with one of the following:

- Dermatologist
- Allergist
- Immunologist

**AND**

**4** - One of the following:

**4.1** Patient has achieved clear or almost clear skin and the request is for Nemluvio 30 milligrams given every 8 weeks (authorize approval length for 12 months)

**OR**

**4.2** Patient has not yet achieved clear or almost clear skin and the request is for Nemluvio 30 milligrams given every 4 weeks (authorize approval length for 6 months)

| Product Name:Nemluvio                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                       |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Prurigo Nodularis     |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                             | 6 month(s)            |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of prurigo nodularis</p> <p><b>AND</b></p> <p><b>2</b> - Patient has greater than or equal to 20 nodular lesions</p> <p><b>AND</b></p> <p><b>3</b> - One of the following:</p> <p><b>3.1</b> Failure to at least ONE previous prurigo nodularis treatment(s) (e.g., topical corticosteroids, topical calcineurin inhibitors, topical capsaicin) as confirmed by claims history or submission of medical records</p> |                       |

**OR**

**3.2** History of contraindication or intolerance to ALL other prurigo nodularis treatment(s) (e.g., topical corticosteroids, topical calcineurin inhibitors, topical capsaicin) (please specify contraindication or intolerance)

**AND**

**4** - One of the following:

**4.1** Failure to Dupixent (dupilumab) as confirmed by claims history or submission of medical records

**OR**

**4.2** History of contraindication or intolerance to Dupixent (dupilumab) (please specify contraindication or intolerance)

**OR**

**4.3** Patient is currently on Nemluvio therapy as confirmed by claims history or submission of medical records

**AND**

**5** - Patient is not receiving Nemluvio in combination with either of the following for the treatment of the same indication:

- Biologic immunomodulator [e.g., Adbry (tralokinumab-ldrm), Dupixent (dupilumab), Ebglyss (lebrikizumab-lbkz)]
- Janus kinase inhibitor [e.g., Cibinqo (abrocitinib), Opzelura (topical ruxolitinib), Rinvoq (upadacitinib), Xeljanz/XR (tofacitinib)]

**AND**

**6** - Prescribed by, or in consultation with, one of the following:



- Dermatologist
- Allergist
- Immunologist

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                     |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Nemluvio                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                     |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Prurigo Nodularis   |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 12 month(s)         |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p>1 - Documentation of positive clinical response to Nemluvio therapy</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Patient is not receiving Nemluvio in combination with either of the following for the treatment of the same indication:</p> <ul style="list-style-type: none"> <li>• Biologic immunomodulator [e.g., Adbry (tralokinumab-ldrm), Dupixent (dupilumab), Ebglyss (lebrikizumab-lbkz)]</li> <li>• Janus kinase inhibitor [e.g., Cibinqo (abrocitinib), Opzelura (topical ruxolitinib), Rinvoq (upadacitinib), Xeljanz/XR (tofacitinib)]</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p>3 - Prescribed by or in consultation with one of the following:</p> <ul style="list-style-type: none"> <li>• Dermatologist</li> <li>• Allergist</li> <li>• Immunologist</li> </ul> |                     |

## 2 . Background

| Benefit/Coverage/Program Information                   |                                      |                                 |              |
|--------------------------------------------------------|--------------------------------------|---------------------------------|--------------|
| Table 1: Relative potencies of topical corticosteroids |                                      |                                 |              |
| Class                                                  | Drug                                 | Dosage Form                     | Strength (%) |
| Very high potency                                      | Augmented betamethasone dipropionate | Ointment, gel                   | 0.05         |
|                                                        | Clobetasol propionate                | Cream, foam, ointment           | 0.05         |
|                                                        | Diflorasone diacetate                | Ointment                        | 0.05         |
|                                                        | Halobetasol propionate               | Cream, ointment                 | 0.05         |
| High Potency                                           | Amcinonide                           | Cream, lotion, ointment         | 0.1          |
|                                                        | Augmented betamethasone dipropionate | Cream, lotion                   | 0.05         |
|                                                        | Betamethasone dipropionate           | Cream, foam, ointment, solution | 0.05         |
|                                                        | Desoximetasone                       | Cream, ointment                 | 0.25         |
|                                                        | Desoximetasone                       | Gel                             | 0.05         |
|                                                        | Diflorasone diacetate                | Cream                           | 0.05         |
|                                                        | tridifloronide                       | Cream, gel, ointment, solution  | 0.05         |
|                                                        | Halcinonide                          | Cream, ointment                 | 0.1          |
|                                                        | Mometasone furoate                   | Ointment                        | 0.1          |
| Medium potency                                         | Triamcinolone acetonide              | Cream, ointment                 | 0.5          |
|                                                        | Betamethasone valerate               | Cream, foam, lotion, ointment   | 0.1          |
|                                                        | Clocortolone pivalate                | Cream                           | 0.1          |
|                                                        | Desoximetasone                       | Cream                           | 0.05         |
|                                                        | Fluocinolone acetonide               | Cream, ointment                 | 0.025        |
|                                                        | Flurandrenolide                      | Cream, ointment, lotion         | 0.05         |
|                                                        | Fluticasone propionate               | Cream                           | 0.05         |
|                                                        | Fluticasone propionate               | Ointment                        | 0.005        |
|                                                        | Mometasone furoate                   | Cream, lotion                   | 0.1          |
| Lower-medium potency                                   | Triamcinolone acetonide              | Cream, ointment, lotion         | 0.1          |
|                                                        | Hydrocortisone butyrate              | Cream, ointment, solution       | 0.1          |
|                                                        | Hydrocortisone probutate             | Cream                           | 0.1          |
|                                                        | Hydrocortisone valerate              | Cream, ointment                 | 0.2          |
| Low potency                                            | Prednicarbate                        | Cream                           | 0.1          |
|                                                        | Alclometasone dipropionate           | Cream, ointment                 | 0.05         |
| Low potency                                            | Desonide                             | Cream, gel, foam, ointment      | 0.05         |

|                   |                        |                                      |              |
|-------------------|------------------------|--------------------------------------|--------------|
| Lowest<br>potency | Fluocinolone acetonide | Cream, solution                      | 0.01         |
|                   | Dexamethasone          | Cream                                | 0.1          |
|                   | Hydrocortisone         | Cream, lotion, ointment,<br>solution | 0.25, 0.5, 1 |
|                   | Hydrocortisone acetate | Cream, ointment                      | 0.5-1        |

### 3 . Revision History

| Date      | Notes                                                                                                                                                                   |
|-----------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 8/19/2025 | Updated patient is not receiving Nemluvio in combo language to specify for treatment of same indication. Updated reauthorization duration in atopic dermatitis section. |

Nerlynx



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-422570                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Guideline Name</b> | Nerlynx                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 11/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                      |                                            |
|----------------------|--------------------------------------------|
| Product Name:Nerlynx |                                            |
| Diagnosis            | Early-Stage or Node-Positive Breast Cancer |
| Approval Length      | 12 month(s)                                |
| Guideline Type       | Prior Authorization                        |

**Approval Criteria**

**1** - ALL of the following:

**1.1** Diagnosis of early-stage breast cancer

**AND**

**1.2** Disease is human epidermal growth factor receptor 2 (HER2)-positive

**AND**

**1.3** Used as extended adjuvant therapy following adjuvant trastuzumab containing therapy (e.g., Herceptin, Kanjinti)

**AND**

**1.4** Patient will not have more than 12 months of treatment per occurrence\*

**OR**

**2** - ALL of the following:

**2.1** Diagnosis of node positive breast cancer

**AND**

**2.2** Disease is hormone receptor (HR)-positive and HER2-positive

**AND**

**2.3** Used as extended adjuvant therapy following adjuvant trastuzumab containing therapy (e.g., Herceptin, Kanjinti)

**AND**

**2.4** Patient has a perceived high risk of recurrence

**AND**

**2.5** Patient will not have more than 12 months of treatment per occurrence\*

|       |                                                               |
|-------|---------------------------------------------------------------|
| Notes | *Duration of coverage is limited to 12 months per occurrence. |
|-------|---------------------------------------------------------------|

|                                                                                                                                                                                                                                                                                                                                                                                                 |                                      |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|
| Product Name:Nerlynx                                                                                                                                                                                                                                                                                                                                                                            |                                      |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                       | Advanced or Metastatic Breast Cancer |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                 | 12 month(s)                          |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                   | Initial Authorization                |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                  | Prior Authorization                  |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - ALL of the following:</p> <p><b>1.1</b> Diagnosis of advanced or metastatic breast cancer</p> <p><b>AND</b></p> <p><b>1.2</b> Disease is human epidermal growth factor receptor 2 (HER2)-positive</p> <p><b>AND</b></p> <p><b>1.3</b> Patient has received two or more prior anti-HER2 based regimens in metastatic setting</p> <p><b>AND</b></p> |                                      |

**1.4** Will be used in combination with capecitabine (generic Xeloda)

**OR**

**2** - BOTH of the following:

**2.1** Diagnosis of stage IV (M1) breast cancer

**AND**

**2.2** ONE of the following:

**2.2.1** BOTH of the following:

- Disease is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative disease
- Patient has already received a CDK4/6 inhibitor therapy

**OR**

**2.2.2** Triple negative disease

|                                                                                                |                                     |
|------------------------------------------------------------------------------------------------|-------------------------------------|
| Product Name:Nerlynx                                                                           |                                     |
| Diagnosis                                                                                      | Breast Cancer with Brain Metastases |
| Approval Length                                                                                | 12 month(s)                         |
| Therapy Stage                                                                                  | Initial Authorization               |
| Guideline Type                                                                                 | Prior Authorization                 |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of breast cancer</p> <p><b>AND</b></p> |                                     |

**2** - Patient has brain metastases

**AND**

**3** - Disease is human epidermal growth factor receptor 2 (HER2)-positive

**AND**

**4** - Used in combination with ONE of the following:

- capecitabine (generic Xeloda)
- Paclitaxel

|                                                                                                                                                                                                                                                                                              |                       |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Nerlynx                                                                                                                                                                                                                                                                         |                       |
| Diagnosis                                                                                                                                                                                                                                                                                    | Cervical Cancer       |
| Approval Length                                                                                                                                                                                                                                                                              | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                               | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of recurrent or metastatic cervical cancer</p> <p><b>AND</b></p> <p><b>2</b> - Disease is human epidermal growth factor receptor 2 (HER2)-positive</p> <p><b>AND</b></p> <p><b>3</b> - Used as second-line or subsequent therapy</p> |                       |



|                                                                                                                           |                                                                                            |
|---------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------|
| Product Name:Nerlynx                                                                                                      |                                                                                            |
| Diagnosis                                                                                                                 | Advanced or Metastatic Breast Cancer, Breast Cancer with Brain Metastases, Cervical Cancer |
| Approval Length                                                                                                           | 12 month(s)                                                                                |
| Therapy Stage                                                                                                             | Reauthorization                                                                            |
| Guideline Type                                                                                                            | Prior Authorization                                                                        |
| <b>Approval Criteria</b><br><br><b>1</b> - Patient does not show evidence of progressive disease while on Nerlynx therapy |                                                                                            |

|                                                                                                                                                |                           |
|------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Nerlynx                                                                                                                           |                           |
| Diagnosis                                                                                                                                      | NCCN Recommended Regimens |
| Approval Length                                                                                                                                | 12 month(s)               |
| Therapy Stage                                                                                                                                  | Initial Authorization     |
| Guideline Type                                                                                                                                 | Prior Authorization       |
| <b>Approval Criteria</b><br><br><b>1</b> - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium |                           |

|                                                                                                           |                           |
|-----------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Nerlynx                                                                                      |                           |
| Diagnosis                                                                                                 | NCCN Recommended Regimens |
| Approval Length                                                                                           | 12 month(s)               |
| Therapy Stage                                                                                             | Reauthorization           |
| Guideline Type                                                                                            | Prior Authorization       |
| <b>Approval Criteria</b><br><br><b>1</b> - Documentation of positive clinical response to Nerlynx therapy |                           |

## 2 . Revision History

| Date       | Notes                                                                      |
|------------|----------------------------------------------------------------------------|
| 10/22/2025 | Updated formularies to include IN for eff 11/1/25. Minor cosmetic updates. |

Nexavar



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-435228                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Guideline Name</b> | Nexavar                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 12/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                                                |                            |
|------------------------------------------------|----------------------------|
| Product Name: Brand Nexavar, generic sorafenib |                            |
| Diagnosis                                      | Renal Cell Carcinoma (RCC) |
| Approval Length                                | 12 month(s)                |
| Therapy Stage                                  | Initial Authorization      |
| Guideline Type                                 | Prior Authorization        |

**Approval Criteria**

1 - Diagnosis of advanced renal cell carcinoma (RCC)

Product Name: Brand Nexavar, generic sorafenib

|           |                          |
|-----------|--------------------------|
| Diagnosis | Hepatocellular Carcinoma |
|-----------|--------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

1 - Diagnosis of hepatocellular carcinoma

**AND**

2 - ONE of the following:

- Disease is unresectable
- Used as subsequent-line therapy

Product Name: Brand Nexavar, generic sorafenib

|           |                |
|-----------|----------------|
| Diagnosis | Thyroid Cancer |
|-----------|----------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

1 - ALL of the following:

**1.1** Diagnosis of ONE of the following:

- Follicular carcinoma
- Papillary carcinoma

**AND**

**1.2** Disease is ONE of the following:

- Unresectable locoregional recurrent or persistent
- Metastatic

**AND**

**1.3** ONE of the following:

- Patient has symptomatic disease
- Patient has progressive disease

**AND**

**1.4** Disease is refractory to radioactive iodine treatment

**OR**

**2** - BOTH of the following:

**2.1** Diagnosis of medullary thyroid carcinoma

**AND**

**2.2** Disease is ONE of the following:

- Recurrent
- Metastatic

|                                                                                                                                                                                                                                                       |                       |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name: Brand Nexavar, generic sorafenib                                                                                                                                                                                                        |                       |
| Diagnosis                                                                                                                                                                                                                                             | Soft Tissue Sarcoma   |
| Approval Length                                                                                                                                                                                                                                       | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                         | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                        | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of ONE of the following:</p> <ul style="list-style-type: none"> <li>• Angiosarcoma</li> <li>• Desmoid tumors/aggressive fibromatosis</li> <li>• Solitary fibrous tumor/hemangiopericytoma</li> </ul> |                       |

|                                                                                                                                                                                                                                                                 |                       |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name: Brand Nexavar, generic sorafenib                                                                                                                                                                                                                  |                       |
| Diagnosis                                                                                                                                                                                                                                                       | Bone Cancer           |
| Approval Length                                                                                                                                                                                                                                                 | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                   | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                  | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - BOTH of the following:</p> <p>1.1 Diagnosis of chordoma</p> <p style="text-align: center;"><b>AND</b></p> <p>1.2 Disease is recurrent</p> <p style="text-align: center;"><b>OR</b></p> <p>2 - BOTH of the following:</p> |                       |

**2.1 ONE of the following:**

- Diagnosis of osteosarcoma
- Diagnosis of dedifferentiated chondrosarcoma
- Diagnosis of high-grade undifferentiated pleomorphic sarcoma (UPS)

**AND**

**2.2 Not used as first-line therapy**

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                        |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|
| Product Name:Brand Nexavar, generic sorafenib                                                                                                                                                                                                                                                                                                                                                                                                                                           |                        |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Acute Myeloid Leukemia |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 12 month(s)            |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Initial Authorization  |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Prior Authorization    |
| <p><b>Approval Criteria</b></p> <p><b>1 - Diagnosis of acute myeloid leukemia (AML)</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>2 - Patient has FLT3-ITD mutation-positive disease</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>3 - ONE of the following:</b></p> <p><b>3.1 Used for those who are post-allogeneic stem cell transplantation, in remission</b></p> <p style="text-align: center;"><b>OR</b></p> <p><b>3.2 BOTH of the following:</b></p> |                        |

- Patient has relapsed/refractory disease
- Used in combination with azacitidine or decitabine

|                                                |                       |
|------------------------------------------------|-----------------------|
| Product Name: Brand Nexavar, generic sorafenib |                       |
| Diagnosis                                      | Ovarian Cancer        |
| Approval Length                                | 12 month(s)           |
| Therapy Stage                                  | Initial Authorization |
| Guideline Type                                 | Prior Authorization   |

**Approval Criteria**

1 - Diagnosis of ONE of the following:

- Ovarian cancer
- Fallopian tube cancer
- Primary peritoneal cancer

**AND**

2 - ONE of the following:

- Patient has persistent disease
- Patient has recurrent disease

**AND**

3 - Disease is platinum-resistant

**AND**

4 - Used in combination with topotecan

|                                                |
|------------------------------------------------|
| Product Name: Brand Nexavar, generic sorafenib |
|------------------------------------------------|



|                                                                                                                                                                                                                                                                                    |                       |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Diagnosis                                                                                                                                                                                                                                                                          | Salivary Gland Tumor  |
| Approval Length                                                                                                                                                                                                                                                                    | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                      | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                     | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of salivary gland tumor</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Disease is ONE of the following:</p> <ul style="list-style-type: none"> <li>• Recurrent</li> <li>• Unresectable</li> <li>• Metastatic</li> </ul> |                       |

|                                                                                                                                                                                                  |                            |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|
| Product Name:Brand Nexavar, generic sorafenib                                                                                                                                                    |                            |
| Diagnosis                                                                                                                                                                                        | Myeloid/Lymphoid Neoplasms |
| Approval Length                                                                                                                                                                                  | 12 month(s)                |
| Therapy Stage                                                                                                                                                                                    | Initial Authorization      |
| Guideline Type                                                                                                                                                                                   | Prior Authorization        |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of myeloid/lymphoid neoplasm with eosinophilia</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Presence of FLT3 gene rearrangement</p> |                            |

|                                               |
|-----------------------------------------------|
| Product Name:Brand Nexavar, generic sorafenib |
|-----------------------------------------------|

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                       |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Gastrointestinal Stromal Tumor (GIST) |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 12 month(s)                           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Initial Authorization                 |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Prior Authorization                   |
| <p><b>Approval Criteria</b></p> <p><b>1 - Diagnosis of gastrointestinal stromal tumors (GIST)</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>2 - Disease is ONE of the following:</b></p> <ul style="list-style-type: none"> <li>• Unresectable</li> <li>• Progressive</li> <li>• Metastatic</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>3 - ONE of the following:</b></p> <p><b>3.1 Failure to ONE of the following as confirmed by claims history or submission of medical records:</b></p> <ul style="list-style-type: none"> <li>• imatinib (generic for Gleevec)</li> <li>• sunitinib (generic for Sutent)</li> <li>• Qinlock (ripretinib)</li> <li>• Stivarga (regorafenib)</li> </ul> <p style="text-align: center;"><b>OR</b></p> <p><b>3.2 History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication):</b></p> <ul style="list-style-type: none"> <li>• imatinib (generic for Gleevec)</li> <li>• sunitinib (generic for Sutent)</li> <li>• Qinlock (ripretinib)</li> <li>• Stivarga (regorafenib)</li> </ul> |                                       |

|                                                                                                                          |                                                                                                                                                                                                                                         |
|--------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Product Name:Brand Nexavar, generic sorafenib                                                                            |                                                                                                                                                                                                                                         |
| Diagnosis                                                                                                                | Renal Cell Carcinoma (RCC), Hepatocellular Carcinoma, Thyroid Cancer, Soft Tissue Sarcoma, Bone Cancer, Acute Myeloid Leukemia, Ovarian Cancer, Salivary Gland Tumor, Myeloid/Lymphoid Neoplasms, Gastrointestinal Stromal Tumor (GIST) |
| Approval Length                                                                                                          | 12 month(s)                                                                                                                                                                                                                             |
| Therapy Stage                                                                                                            | Reauthorization                                                                                                                                                                                                                         |
| Guideline Type                                                                                                           | Prior Authorization                                                                                                                                                                                                                     |
| <b>Approval Criteria</b><br><br>1 - Patient does not show evidence of progressive disease while on the requested therapy |                                                                                                                                                                                                                                         |

|                                                                                                                                         |                           |
|-----------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Brand Nexavar, generic sorafenib                                                                                           |                           |
| Diagnosis                                                                                                                               | NCCN Recommended Regimens |
| Approval Length                                                                                                                         | 12 month(s)               |
| Therapy Stage                                                                                                                           | Initial Authorization     |
| Guideline Type                                                                                                                          | Prior Authorization       |
| <b>Approval Criteria</b><br><br>1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium |                           |

|                                               |                           |
|-----------------------------------------------|---------------------------|
| Product Name:Brand Nexavar, generic sorafenib |                           |
| Diagnosis                                     | NCCN Recommended Regimens |
| Approval Length                               | 12 month(s)               |
| Therapy Stage                                 | Reauthorization           |
| Guideline Type                                | Prior Authorization       |
|                                               |                           |

### Approval Criteria

1 - Documentation of positive clinical response to the requested therapy

## 2 . Revision History

| Date       | Notes                                                                                                                                                                                                                                                                                                                                                                                     |
|------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 10/31/2025 | Combined formularies. Updated criteria for renal cell carcinoma, hepatocellular carcinoma, thyroid cancer, soft tissue sarcoma, acute myeloid leukemia, salivary gland tumor, and myeloid/lymphoid neoplasms . Moved gastrointestinal stromal tumors out of soft tissue sarcoma into its own section and updated criteria for initial auth. Updated diagnosis header for reauth criteria. |

Nexletol, Nexlizet



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-426278                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Guideline Name</b> | Nexletol, Nexlizet                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 11/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                                 |                       |
|---------------------------------|-----------------------|
| Product Name:Nexletol, Nexlizet |                       |
| Diagnosis                       | Hyperlipidemia        |
| Approval Length                 | 12 month(s)           |
| Therapy Stage                   | Initial Authorization |
| Guideline Type                  | Prior Authorization   |

### **Approval Criteria**

**1 - ONE of the following diagnoses:**

**1.1** Primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH)

**OR**

**1.2** Established cardiovascular disease (CVD) as documented by one of the following:

- coronary artery disease
- symptomatic peripheral arterial disease
- cerebrovascular atherosclerotic disease

**OR**

**1.3** High risk for cardiovascular disease (CVD) as documented by one of the following:

- Diabetes and over 60 years old
- Reynolds risk score greater than 30%
- Coronary artery calcium score greater than 400 Agatston units
- ASCVD risk score greater than or equal to 20% with the American College of Cardiology/American Heart Association (ACC/AHA) risk estimator

**AND**

**2 - Submission of medical records (e.g., chart notes, laboratory values) confirming ONE of the following [prescription claims history may be used in conjunction as confirmation of medication use, dose, and duration]:**

**2.1** Patient has been receiving at least 12 consecutive weeks of high intensity statin therapy [i.e., atorvastatin 40-80 mg (milligrams), rosuvastatin 20-40 mg] and will continue to receive a high intensity statin at maximally tolerated dose

**OR**

**2.2 BOTH of the following:**

**2.2.1** Patient is unable to tolerate high-intensity statin as evidenced by ONE of the following intolerable and persistent (i.e., more than 2 weeks) symptoms:

- Myalgia [muscle symptoms without CK (creatinine kinase) elevations]
- Myositis [muscle symptoms with CK elevations less than 10 times upper limit of normal (ULN)]

**AND**

**2.2.2** Patient has been receiving at least 12 consecutive weeks of low-intensity or moderate-intensity statin therapy [i.e., atorvastatin 10-20 mg, rosuvastatin 5-10 mg, simvastatin greater than or equal to 10 mg, pravastatin greater than or equal to 10 mg, lovastatin 20-40 mg, fluvastatin extended-release 80 mg, fluvastatin 20-40 mg up to 40mg twice daily or Livalo (pitavastatin) greater than or equal to 1 mg] and will continue to receive a low-intensity or moderate-intensity statin at maximally tolerated dose

**OR**

**2.3** Patient is unable to tolerate low or moderate-, and high-intensity statins as evidenced by ONE of the following:

**2.3.1** ONE of the following intolerable and persistent (i.e., more than 2 weeks) symptoms for low or moderate-, and high-intensity statins:

- Myalgia (muscle symptoms without CK elevations)
- Myositis (muscle symptoms with CK elevations less than 10 times ULN)

**OR**

**2.3.2** Patient has a labeled contraindication to all statins as documented in medical records

**OR**

**2.3.3** Patient has experienced rhabdomyolysis or muscle symptoms with statin treatment with CK elevations greater than 10 times ULN

**AND**

**3 - ONE of the following:**

**3.1** Submission of medical records (e.g., laboratory values) confirming ONE of the following LDL-C (low-density lipoprotein cholesterol) values while on maximally tolerated lipid lowering therapy within the last 120 days:

- LDL-C greater than or equal to 100 mg/dL (milligrams/deciliter) with ASCVD
- LDL-C greater than or equal to 130 mg/dL without ASCVD

**OR**

**3.2 BOTH of the following:**

**3.2.1** Submission of medical records (e.g., laboratory values) confirming ONE of the following LDL-C values while on maximally tolerated lipid lowering therapy for a minimum of at least 12 weeks within the last 120 days:

- LDL-C between 55 mg/dL and 99 mg/dL with ASCVD
- LDL-C between 100 mg/dL and 129 mg/dL without ASCVD

**AND**

**3.2.2** Submission of medical records (e.g., chart notes, laboratory values) confirming ONE of the following [prescription claims history may be used in conjunction as confirmation of medication use, dose, and duration]:

**3.2.2.1** Patient has been receiving at least 12 consecutive weeks of ezetimibe (Zetia) therapy as adjunct to maximally tolerated statin therapy

**OR**

**3.2.2.2** Patient has a history of contraindication, or intolerance to ezetimibe

|                                 |                     |
|---------------------------------|---------------------|
| Product Name:Nexleto1, Nexlizet |                     |
| Diagnosis                       | Hyperlipidemia      |
| Approval Length                 | 12 month(s)         |
| Therapy Stage                   | Reauthorization     |
| Guideline Type                  | Prior Authorization |



**Approval Criteria**

1 - Documentation of a positive clinical response to therapy

**AND**

2 - Patient continues to receive statin at maximally tolerated dose (unless patient has documented inability to take statins)

**2 . Revision History**

| Date       | Notes              |
|------------|--------------------|
| 10/22/2025 | Added NM Formulary |

Ninlaro



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-351197                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Guideline Name</b> | Ninlaro                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Washington (ACUWA, ACUWAAHE, ACUWAC)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 9/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                      |                  |
|----------------------|------------------|
| Product Name:Ninlaro |                  |
| Diagnosis            | Multiple Myeloma |
| Approval Length      | 12 month(s)      |

|                                                                      |                       |
|----------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                        | Initial Authorization |
| Guideline Type                                                       | Prior Authorization   |
| <b>Approval Criteria</b><br><b>1 - Diagnosis of multiple myeloma</b> |                       |

|                                                                                                             |                                  |
|-------------------------------------------------------------------------------------------------------------|----------------------------------|
| Product Name:Ninlaro                                                                                        |                                  |
| Diagnosis                                                                                                   | Systemic Light Chain Amyloidosis |
| Approval Length                                                                                             | 12 month(s)                      |
| Therapy Stage                                                                                               | Initial Authorization            |
| Guideline Type                                                                                              | Prior Authorization              |
| <b>Approval Criteria</b><br><b>1 - Diagnosis of relapsed or refractory systemic light chain amyloidosis</b> |                                  |

|                                                                                                                                                                                                                                   |                                                          |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------|
| Product Name:Ninlaro                                                                                                                                                                                                              |                                                          |
| Diagnosis                                                                                                                                                                                                                         | Waldenström Macroglobulinemia/Lymphoplasmacytic Lymphoma |
| Approval Length                                                                                                                                                                                                                   | 12 month(s)                                              |
| Therapy Stage                                                                                                                                                                                                                     | Initial Authorization                                    |
| Guideline Type                                                                                                                                                                                                                    | Prior Authorization                                      |
| <b>Approval Criteria</b><br><b>1 - Diagnosis of Waldenström macroglobulinemia/lymphoplasmacytic lymphoma</b><br><br><p style="text-align: center;"><b>AND</b></p> <b>2 - Used in combination with rituximab and dexamethasone</b> |                                                          |

|                                                                                                                           |                                                                                                              |
|---------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------|
| Product Name:Ninlaro                                                                                                      |                                                                                                              |
| Diagnosis                                                                                                                 | Multiple Myeloma, Systemic Light Chain Amyloidosis, Waldenström Macroglobulinemia/Lymphoplasmacytic Lymphoma |
| Approval Length                                                                                                           | 12 month(s)                                                                                                  |
| Therapy Stage                                                                                                             | Reauthorization                                                                                              |
| Guideline Type                                                                                                            | Prior Authorization                                                                                          |
| <b>Approval Criteria</b><br><br><b>1</b> - Patient does not show evidence of progressive disease while on Ninlaro therapy |                                                                                                              |

|                                                                                                                                                |                           |
|------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Ninlaro                                                                                                                           |                           |
| Diagnosis                                                                                                                                      | NCCN Recommended Regimens |
| Approval Length                                                                                                                                | 12 month(s)               |
| Therapy Stage                                                                                                                                  | Initial Authorization     |
| Guideline Type                                                                                                                                 | Prior Authorization       |
| <b>Approval Criteria</b><br><br><b>1</b> - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium |                           |

|                                                                                                           |                           |
|-----------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Ninlaro                                                                                      |                           |
| Diagnosis                                                                                                 | NCCN Recommended Regimens |
| Approval Length                                                                                           | 12 month(s)               |
| Therapy Stage                                                                                             | Reauthorization           |
| Guideline Type                                                                                            | Prior Authorization       |
| <b>Approval Criteria</b><br><br><b>1</b> - Documentation of positive clinical response to Ninlaro therapy |                           |

## 2 . Revision History

| Date      | Notes                                                  |
|-----------|--------------------------------------------------------|
| 7/30/2025 | Combined formularies. No changes to clinical criteria. |

Nityr



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-436481                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Guideline Name</b> | Nityr                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Pennsylvania (ACUPA)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 12/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                    |             |
|--------------------|-------------|
| Product Name:Nityr |             |
| Approval Length    | 12 month(s) |

|                                                                                       |                     |
|---------------------------------------------------------------------------------------|---------------------|
| Guideline Type                                                                        | Prior Authorization |
| <b>Approval Criteria</b><br><br><b>1 - Diagnosis of hereditary tyrosinemia type 1</b> |                     |

## 2 . Revision History

| Date       | Notes                                                  |
|------------|--------------------------------------------------------|
| 10/31/2025 | Combined formularies. No changes to clinical criteria. |

Nocdurna



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-228222                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Guideline Name</b> | Nocdurna                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State Michigan (ACUMI)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania (ACUPA)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Washington (ACUWA, ACUWAAHE, ACUWAC)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 5/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                       |
|-----------------------|
| Product Name:Nocdurna |
|-----------------------|



|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                       |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of nocturia due to nocturnal polyuria (as defined by nighttime urine production that exceeds one-third of the 24-hour urine production)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Patient wakes at least twice per night on a reoccurring basis to void</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Documented serum sodium level is currently within normal limits of the normal laboratory reference range and has been within normal limits over the previous six months</p> <p style="text-align: center;"><b>AND</b></p> <p><b>4</b> - The patient has been evaluated for other medical causes and has either not responded to, tolerated, or has a contraindication to treatments for identifiable medical causes [e.g., overactive bladder, benign prostatic hyperplasia/lower urinary tract symptoms (BPH/LUTS), elevated post-void residual urine, and heart failure]</p> <p style="text-align: center;"><b>AND</b></p> <p><b>5</b> - Prescriber attests that the risks have been assessed and benefits outweigh the risks</p> |                       |

|                       |                     |
|-----------------------|---------------------|
| Product Name:Nocdurna |                     |
| Approval Length       | 12 month(s)         |
| Therapy Stage         | Reauthorization     |
| Guideline Type        | Prior Authorization |

### Approval Criteria

1 - Documentation of positive clinical response to Nocdurna therapy

**AND**

2 - Patient has routine monitoring for serum sodium levels

**AND**

3 - Prescriber attests that the risks of hyponatremia have been assessed and benefits outweigh the risks

## 2 . Revision History

| Date      | Notes                                                  |
|-----------|--------------------------------------------------------|
| 3/27/2025 | Combined formularies. No changes to clinical criteria. |

Non-Preferred Drugs



## Prior Authorization Guideline

|                       |                                                                                                         |
|-----------------------|---------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-234201                                                                                               |
| <b>Guideline Name</b> | Non-Preferred Drugs                                                                                     |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>Medicaid - Community &amp; State New Jersey (PSI2300)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 6/1/2025 |
|-----------------|----------|

## 1 . Criteria

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|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|
| Product Name:Non-Preferred Drugs                                                                                                                                                                                                                                                                                             |                |
| Approval Length                                                                                                                                                                                                                                                                                                              | 12 month(s)    |
| Guideline Type                                                                                                                                                                                                                                                                                                               | Administrative |
| <p><b>Approval Criteria</b></p> <p>1 - If the requested medication is a behavioral health medication, ONE of the following:</p> <p>1.1 The patient has been receiving treatment with the requested non-preferred behavioral health medication and is new to the plan (enrollment effective date within the past 90 days)</p> |                |

**OR**

**1.2** The patient is currently receiving treatment with the requested non-preferred behavioral health medication in the hospital and must continue upon discharge

**OR**

**2** - ALL of the following:

**2.1** One of the following^:

**2.1.1** Both of the following:

**2.1.1.1** One of the following:

- History of failure to at least THREE preferred alternatives as confirmed by claims history or submission of medical records.\* NOTE: In instances where there are fewer than three preferred alternatives, the patient must have a history of failure to all of the preferred products.
- History of contraindication or intolerance to THREE preferred alternatives (please specify contraindication or intolerance).\* NOTE: In instances where there are fewer than three preferred alternatives, the patient must have a history of contraindication or intolerance to all of the preferred products.

**AND**

**2.1.1.2** One of the following:

**2.1.1.2.1** If the request is for a multi-source brand medication, OR a branded medication with an authorized generic, one of the following:

- The brand is being requested because of an adverse reaction, allergy or sensitivity to a generic/authorized generic equivalent (specify the adverse reaction, allergy, or sensitivity)
- The brand is being requested due to an incomplete response with a generic/authorized generic equivalent, as documented by submission of medical records
- The brand is being requested because transition to a generic/authorized generic equivalent could result in destabilization of the patient.

- Special clinical circumstances exist that preclude the use of a generic/authorized generic equivalent of the brand medication for the patient (document special clinical circumstances)

**OR**

**2.1.1.2.2** If the request is for a generic when there is a brand available and the brand is the preferred formulation, one of the following:

- The generic is being requested because of an adverse reaction, allergy or sensitivity to the brand (specify the adverse reaction, allergy, or sensitivity).
- The generic is being requested due to an incomplete response with the brand, as documented by submission of medical records.
- The generic is being requested because transition to the brand could result in destabilization of the patient.
- Special clinical circumstances exist that preclude the use of the brand equivalent of the generic medication for the patient (document special clinical circumstances).

**OR**

**2.1.2** There are no preferred formulary alternatives for the requested drug.

**AND**

**2.2** One of the following:

**2.2.1** The requested drug must be used for an FDA-approved indication

**OR**

**2.2.2** The use of this drug is supported by information from ONE of the following appropriate compendia of current literature:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopeia-National Formulary (USP-NF )

**AND**

**2.3** The drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plan's program.

|       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Notes | <p>* Prior trials of formulary/PDL alternatives must sufficiently demonstrate that the formulary/PDL alternatives are either ineffective or inappropriate at the time of the request. PDL Link: <a href="https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html</a>.</p> <p>^NJ Psych Panel (any mental health prescriber) is not subject to this criteria.</p> |
|-------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|
| Product Name: PA Required Medications For a New Indication Not Addressed in Drug Specific Guideline                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 12 month(s)    |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Administrative |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Both of the following:</p> <p><b>1.1</b> Diagnosis is consistent with an indication listed in the product's FDA-approved prescribing information (or package insert)</p> <p><b>AND</b></p> <p><b>1.2</b> All of the following labeling requirements have been met:</p> <p><b>1.2.1</b> All requirements listed in the "Indications and Use" have been met (e.g., pre-requisite treatment, any testing requirements have been met, etc.)</p> <p><b>AND</b></p> <p><b>1.2.2</b> Prescribed medication is approved for the patient's age</p> |                |

**AND**

**1.2.3** “Dosage and Administration” section of the prescribing information (or package insert) has been met

**AND**

**2** - The drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plan’s program

**AND**

**3** - If the requested medication is non-preferred, patient meets the non-preferred criteria as applicable

|       |                                                                                                                        |
|-------|------------------------------------------------------------------------------------------------------------------------|
| Notes | These criteria come from PA Required Medications For a New Indication Not Addressed in Drug Specific Guideline policy. |
|-------|------------------------------------------------------------------------------------------------------------------------|

## 2 . Revision History

| Date     | Notes                                                                           |
|----------|---------------------------------------------------------------------------------|
| 4/8/2025 | Added new criteria for New Indications Not Addressed in Drug Specific Guideline |

Northera



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-242257                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Guideline Name</b> | Northera                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania (ACUPA)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 7/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                                                 |             |
|-------------------------------------------------|-------------|
| Product Name: Brand Northera, generic droxidopa |             |
| Approval Length                                 | 12 month(s) |



|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                       |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of symptomatic neurogenic orthostatic hypotension (nOH) as defined by ONE of the following when an upright position is assumed or when using a head-up tilt-table testing at an angle of at least 60 degrees:</p> <ul style="list-style-type: none"> <li>• At least a 20 millimeters of mercury (mm Hg) fall in systolic pressure</li> <li>• At least a 10 mm Hg fall in diastolic pressure</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - nOH caused by ONE of the following:</p> <ul style="list-style-type: none"> <li>• Primary autonomic failure (e.g., Parkinson's disease, multiple system atrophy, and pure autonomic failure)</li> <li>• Dopamine beta-hydroxylase deficiency</li> <li>• Non-diabetic autonomic neuropathy</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Diagnostic evaluation has excluded other causes associated with orthostatic hypotension (e.g., congestive heart failure, fluid restriction, malignancy)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>4</b> - The patient has tried at least TWO of the following non-pharmacologic interventions:</p> <ul style="list-style-type: none"> <li>• Discontinuation of drugs which can cause orthostatic hypotension [e.g., diuretics, antihypertensive medications (primarily sympathetic blockers), anti-anginal drugs (nitrates), alpha-adrenergic antagonists, and antidepressants]</li> <li>• Raising the head of the bed 10 to 20 degrees</li> <li>• Compression garments to the lower extremities or abdomen</li> <li>• Physical maneuvers to improve venous return (e.g., regular modest-intensity exercise)</li> <li>• Increased salt and water intake, if appropriate</li> <li>• Avoiding precipitating factors (e.g., overexertion in hot weather, arising too quickly from supine to sitting or standing)</li> </ul> |                       |

**AND**

**5** - No previous diagnosis of supine hypertension

**AND**

**6** - Prescribed by or in consultation with ONE of the following specialists:

- Cardiologist
- Neurologist
- Nephrologist

**AND**

**7** - ONE of the following:

**7.1** Failure (after a trial of at least 30 days) of BOTH of the following confirmed by claims history or submitted medical records:

- fludrocortisone (generic Florinef)
- midodrine (generic ProAmatine)

**OR**

**7.2** History of contraindication or intolerance to BOTH of the following:

- fludrocortisone (generic Florinef)
- midodrine (generic ProAmatine)

|                                                 |                     |
|-------------------------------------------------|---------------------|
| Product Name: Brand Northera, generic droxidopa |                     |
| Approval Length                                 | 12 month(s)         |
| Therapy Stage                                   | Reauthorization     |
| Guideline Type                                  | Prior Authorization |
|                                                 |                     |

**Approval Criteria**

1 - Documentation of positive clinical response to the requested therapy

**AND**

2 - Physiological countermeasures for neurogenic orthostatic hypotension (nOH) continue to be employed

**2 . Revision History**

| Date      | Notes                                                  |
|-----------|--------------------------------------------------------|
| 4/23/2025 | Combined formularies. No changes to clinical criteria. |

Nourianz



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-164688                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Guideline Name</b> | Nourianz                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 3/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                       |                       |
|-----------------------|-----------------------|
| Product Name:Nourianz |                       |
| Approval Length       | 12 month(s)           |
| Therapy Stage         | Initial Authorization |
| Guideline Type        | Prior Authorization   |

## Approval Criteria

**1** - Diagnosis of Parkinson's disease

**AND**

**2** - Used as adjunctive treatment to levodopa/carbidopa in patients experiencing "off" episodes

**AND**

**3** - ONE of the following:

**3.1** Failure to TWO anti-Parkinson's disease therapies from the following adjunctive pharmacotherapy classes (trial must be from two different classes) as confirmed by claims history or submission of medical records:

- Dopamine agonists (e.g., pramipexole, ropinirole)
- Catechol-O-methyl transferase (COMT) inhibitors (e.g., entacapone)
- Monoamine oxidase (MAO) B inhibitors (e.g., rasagiline, selegiline)

**OR**

**3.2** History of contraindication or intolerance to ALL anti-Parkinson's disease therapy from the following adjunctive pharmacotherapy classes (trial must be from all classes) (please specify intolerance or contraindication):

- Dopamine agonists (e.g., pramipexole, ropinirole)
- Catechol-O-methyl transferase (COMT) inhibitors (e.g., entacapone)
- Monoamine oxidase (MAO) B inhibitors (e.g., rasagiline, selegiline)

|                       |                     |
|-----------------------|---------------------|
| Product Name:Nourianz |                     |
| Approval Length       | 12 month(s)         |
| Therapy Stage         | Reauthorization     |
| Guideline Type        | Prior Authorization |

**Approval Criteria**

1 - Documentation of positive clinical response to Nourianz therapy

**AND**

2 - Patient will continue to receive treatment with a carbidopa/levodopa-containing medication

**2 . Revision History**

| Date     | Notes                                              |
|----------|----------------------------------------------------|
| 2/4/2025 | Updated formularies. Updated initial auth duration |

Nubeqa



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-423189                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Guideline Name</b> | Nubeqa                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 11/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                     |                       |
|---------------------|-----------------------|
| Product Name:Nubeqa |                       |
| Diagnosis           | Prostate Cancer       |
| Approval Length     | 12 month(s)           |
| Therapy Stage       | Initial Authorization |

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Prior Authorization |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1 - Diagnosis of prostate cancer</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>2 - ONE of the following:</b></p> <p><b>2.1 BOTH of the following:</b></p> <p><b>2.1.1</b> Disease is non-metastatic</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2.1.2</b> Disease is castration-resistant</p> <p style="text-align: center;"><b>OR</b></p> <p><b>2.2 BOTH of the following:</b></p> <p><b>2.2.1</b> Disease is metastatic</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2.2.2</b> Disease is castration-sensitive</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3 - ONE of the following:</b></p> <p><b>3.1</b> Used in combination with a gonadotropin-releasing hormone (GnRH) analog [e.g., Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix)]</p> |                     |



**OR**

**3.2** Patient has had a bilateral orchiectomy

|                                                                                                                          |                     |
|--------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Nubeqa                                                                                                      |                     |
| Diagnosis                                                                                                                | Prostate Cancer     |
| Approval Length                                                                                                          | 12 month(s)         |
| Therapy Stage                                                                                                            | Reauthorization     |
| Guideline Type                                                                                                           | Prior Authorization |
| <b>Approval Criteria</b><br><br><b>1</b> - Patient does not show evidence of progressive disease while on Nubeqa therapy |                     |

|                                                                                                                                                |                           |
|------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Nubeqa                                                                                                                            |                           |
| Diagnosis                                                                                                                                      | NCCN Recommended Regimens |
| Approval Length                                                                                                                                | 12 month(s)               |
| Therapy Stage                                                                                                                                  | Initial Authorization     |
| Guideline Type                                                                                                                                 | Prior Authorization       |
| <b>Approval Criteria</b><br><br><b>1</b> - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium |                           |

|                     |                           |
|---------------------|---------------------------|
| Product Name:Nubeqa |                           |
| Diagnosis           | NCCN Recommended Regimens |
| Approval Length     | 12 month(s)               |
| Therapy Stage       | Reauthorization           |
| Guideline Type      | Prior Authorization       |

**Approval Criteria**

1 - Documentation of positive clinical response to Nubeqa therapy

**2 . Revision History**

| Date       | Notes                                               |
|------------|-----------------------------------------------------|
| 10/16/2025 | Updated formularies to add ACUIN for eff 11/1/2025. |

Nucala



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-397195                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Guideline Name</b> | Nucala                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 10/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                                                          |                                                                 |
|----------------------------------------------------------|-----------------------------------------------------------------|
| Product Name:Nucala auto-injector and pre-filled syringe |                                                                 |
| Diagnosis                                                | Eosinophilic Granulomatosis with Polyangiitis (EGPA)            |
| Approval Length                                          | 12 month(s)                                                     |
| Therapy Stage                                            | Initial Authorization - Transitioning from UHC medical benefits |
| Guideline Type                                           | Prior Authorization                                             |

### Approval Criteria

**1** - Patient has been established on therapy with Nucala under an active UnitedHealthcare medical benefit prior authorization for the treatment of EGPA

**AND**

**2** - Documentation of positive clinical response to Nucala therapy as demonstrated by at least ONE of the following

- Reduction in the frequency and/or severity of relapses
- Reduction or discontinuation of doses of corticosteroids and/or immunosuppressant
- Disease remission
- Reduction in severity or frequency of EGPA-related symptoms

**AND**

**3** - Patient is not receiving Nucala in combination with ONE of the following for treatment of the same indication:

- Anti-interleukin 5 therapy [e.g., Cinqair (reslizumab), Fasenra (benralizumab)]
- Anti-IgE therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor therapy [e.g., Tezspire (tezepelumab)]

**AND**

**4** - Prescribed by one of the following

- Allergist
- Immunologist
- Pulmonologist
- Rheumatologist

Product Name:Nucala auto-injector and pre-filled syringe

|           |                                                      |
|-----------|------------------------------------------------------|
| Diagnosis | Eosinophilic Granulomatosis with Polyangiitis (EGPA) |
|-----------|------------------------------------------------------|

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                     |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------|
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 12 month(s)                                                         |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Initial Authorization – Not transitioning from UHC medical benefits |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Prior Authorization                                                 |
| <p><b>Approval Criteria</b></p> <p><b>1 - Diagnosis of relapsing or refractory eosinophilic granulomatosis with polyangiitis (EGPA) as defined by ALL of the following:</b></p> <p><b>1.1 Diagnosis of EGPA</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>1.2 Past medical history or presence of asthma</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>1.3 Presence of at least TWO of the following characteristics typical of EGPA:</b></p> <p><b>1.3.1 Histopathological evidence of ALL of the following:</b></p> <ul style="list-style-type: none"> <li>• Eosinophilic vasculitis</li> <li>• Perivascular eosinophilic infiltration</li> <li>• Eosinophil-rich granulomatous inflammation</li> </ul> <p style="text-align: center;"><b>OR</b></p> <p><b>1.3.2 Neuropathy, mono or poly (motor deficit or nerve conduction abnormality)</b></p> <p style="text-align: center;"><b>OR</b></p> <p><b>1.3.3 Pulmonary infiltrates, non-fixed</b></p> <p style="text-align: center;"><b>OR</b></p> |                                                                     |

**1.3.4** Sino-nasal abnormality

**OR**

**1.3.5** Cardiomyopathy [established by echocardiography or magnetic resonance imaging (MRI)]

**OR**

**1.3.6** Glomerulonephritis (hematuria, red cell casts, proteinuria)

**OR**

**1.3.7** Alveolar hemorrhage

**OR**

**1.3.8** Palpable purpura

**OR**

**1.3.9** Anti-neutrophil cytoplasmic antibody (ANCA) positive

**AND**

**1.4** History of relapsing or refractory disease defined as ONE of the following:

**1.4.1** Relapsing disease as defined as a past history (within the past 2 years) of at least one EGPA relapse (requiring additional or dose escalation of corticosteroids or immunosuppressant, or hospitalization)

**OR**

**1.4.2** Refractory disease as defined as failure to attain remission within the prior 6 months following induction treatment with standard therapy regimens

**AND**

**2** - Patient is currently taking standard therapy [i.e., systemic glucocorticoids (e.g., prednisone, methylprednisolone)] with or without immunosuppressive therapy (e.g., cyclophosphamide, rituximab) as supported by claims history or submitted medical records

**AND**

**3** - Patient is not receiving Nucala in combination with ONE of the following for treatment of the same indication:

- Anti-interleukin 5 therapy [e.g., Cinqair (reslizumab), Fasenra (benralizumab)]
- Anti-IgE (immunoglobulin E) therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor therapy [e.g., Tezspire (tezepelumab)]

**AND**

**4** - Prescribed by ONE of the following:

- Allergist
- Immunologist
- Pulmonologist
- Rheumatologist

|                                                          |                                                      |
|----------------------------------------------------------|------------------------------------------------------|
| Product Name:Nucala auto-injector and pre-filled syringe |                                                      |
| Diagnosis                                                | Eosinophilic Granulomatosis with Polyangiitis (EGPA) |
| Approval Length                                          | 12 month(s)                                          |
| Therapy Stage                                            | Reauthorization                                      |
| Guideline Type                                           | Prior Authorization                                  |
| <b>Approval Criteria</b>                                 |                                                      |

**1** - Documentation of positive clinical response to Nucala therapy as demonstrated by at least ONE of the following:

**1.1** Reduction in the frequency and/or severity of relapses

**OR**

**1.2** Reduction or discontinuation of doses of corticosteroids and/or immunosuppressant

**OR**

**1.3** Disease remission

**OR**

**1.4** Reduction in severity or frequency of eosinophilic granulomatosis with polyangiitis (EGPA)-related symptoms

**AND**

**2** - Patient is not receiving Nucala in combination with ONE of the following for treatment of the same indication:

- Anti-interleukin 5 therapy [e.g., Cinqair (reslizumab), Fasenra (benralizumab)]
- Anti-IgE (immunoglobulin E) therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor therapy [e.g., Tezspire (tezepelumab)]

|                                                          |                                                                 |
|----------------------------------------------------------|-----------------------------------------------------------------|
| Product Name:Nucala auto-injector and pre-filled syringe |                                                                 |
| Diagnosis                                                | Severe Asthma                                                   |
| Approval Length                                          | 12 month(s)                                                     |
| Therapy Stage                                            | Initial Authorization - Transitioning from UHC medical benefits |
| Guideline Type                                           | Prior Authorization                                             |



### **Approval Criteria**

**1** - Patient has been established on therapy with Nucala under an active UnitedHealthcare medical benefit prior authorization for the treatment of severe asthma

**AND**

**2** - Documentation of positive clinical response to Nucala therapy as demonstrated by at least ONE of the following

- Reduction in the frequency of exacerbations
- Decreased utilization of rescue medications
- Increase in percent predicted FEV1 from pretreatment baseline
- Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.)
- Reduction in oral corticosteroid requirements

**AND**

**3** - Nucala is being used in combination with an inhaled corticosteroid (ICS) containing maintenance medication [e.g., Advair/AirDuo (fluticasone/salmeterol), Breo Ellipta (fluticasone furoate/vilanterol), Symbicort (budesonide/ formoterol), Trelegy Ellipta (fluticasone furoate/umeclidinium/vilanterol)]

**AND**

**4** - Patient is not receiving Nucala in combination with ONE of the following for treatment of the same indication:

- Anti-interleukin 5 therapy [e.g., Cinqair (reslizumab), Fasenra (benralizumab)]
- Anti-IgE therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

**AND**

**5** - Prescribed by ONE of the following:

- Allergist
- Immunologist
- Pulmonologist

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                     |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------|
| Product Name:Nucala auto-injector and pre-filled syringe                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                     |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Severe Asthma                                                       |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 12 month(s)                                                         |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Initial Authorization – Not transitioning from UHC medical benefits |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Prior Authorization                                                 |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of severe asthma</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Classification of asthma as uncontrolled or inadequately controlled as defined by at least ONE of the following:</p> <p>    <b>2.1</b> Poor symptom control [e.g., Asthma Control Questionnaire (ACQ) score consistently greater than 1.5 or Asthma Control Test (ACT) score consistently less than 20]</p> <p style="text-align: center;"><b>OR</b></p> <p>    <b>2.2</b> Two or more bursts of systemic corticosteroids for at least 3 days each in the previous 12 months</p> <p style="text-align: center;"><b>OR</b></p> <p>    <b>2.3</b> Asthma-related emergency treatment (e.g., emergency room visit, hospital admission, or unscheduled physician's office visit for nebulizer or other urgent treatment)</p> |                                                                     |

**OR**

**2.4** Airflow limitation [e.g., after appropriate bronchodilator withhold forced expiratory volume in 1 second (FEV1) less than 80% predicted (in the face of reduced FEV1/forced vital capacity [FVC] defined as less than the lower limit of normal)]

**OR**

**2.5** Patient is currently dependent on oral corticosteroids for the treatment of asthma

**AND**

**3** - Submission of medical records (e.g., chart notes, laboratory values, etc.) confirming asthma is an eosinophilic phenotype as defined by a baseline (pre-treatment) peripheral blood eosinophil level greater than or equal to 150 cells per microliter

**AND**

**4** - Nucala will be used in combination with ONE of the following:

**4.1** ONE maximally-dosed (appropriately adjusted for age) combination inhaled corticosteroid (ICS)/long-acting beta2 agonist (LABA) [e.g., Advair/AirDuo Respiclick (fluticasone propionate/salmeterol), Symbicort (budesonide/formoterol), Breo Ellipta (fluticasone furoate/vilanterol)]

**OR**

**4.2** Combination therapy including BOTH of the following:

**4.2.1** ONE maximally-dosed (appropriately adjusted for age) ICS product [e.g., ciclesonide (Alvesco), mometasone furoate (Asmanex), beclomethasone dipropionate (QVAR)]

**AND**

**4.2.2** ONE additional asthma controller medication [e.g., LABA - olodaterol (Striverdi) or indacaterol (Arcapta); leukotriene receptor antagonist - montelukast (Singulair); theophylline]

**AND**

**5** - Patient is not receiving Nucala in combination with ONE of the following for treatment of the same indication:

- Anti-interleukin 5 therapy [e.g., Cinqair (reslizumab), Fasenra (benralizumab)]
- Anti-IgE (immunoglobulin E) therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

**AND**

**6** - Prescribed by ONE of the following:

- Allergist
- Immunologist
- Pulmonologist

**AND**

**7** - ONE of the following:

- Failure to a 4 month trial of Fasenra (benralizumab) as confirmed by claims history or submitted medical records
- History of contraindication or intolerance to Fasenra (benralizumab) (please specify intolerance or contraindication)

|                                                          |                     |
|----------------------------------------------------------|---------------------|
| Product Name:Nucala auto-injector and pre-filled syringe |                     |
| Diagnosis                                                | Severe Asthma       |
| Approval Length                                          | 12 month(s)         |
| Therapy Stage                                            | Reauthorization     |
| Guideline Type                                           | Prior Authorization |
| <b>Approval Criteria</b>                                 |                     |

**1** - Documentation of positive clinical response to Nucala therapy as demonstrated by at least ONE of the following:

**1.1** Reduction in the frequency of exacerbations

**OR**

**1.2** Decreased utilization of rescue medications

**OR**

**1.3** Increase in percent predicted forced expiratory volume in 1 second (FEV1) from pretreatment baseline

**OR**

**1.4** Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.)

**OR**

**1.5** Reduction in oral corticosteroid requirements

**AND**

**2** - Nucala is being used in combination with an inhaled corticosteroid (ICS)-containing maintenance medication [e.g., Advair/AirDuo (fluticasone/salmeterol), Breo Ellipta (fluticasone furoate/vilanterol), Symbicort (budesonide/ formoterol), Trelegy Ellipta (fluticasone furoate/umeclidinium/vilanterol)]

**AND**

**3** - Patient is not receiving Nucala in combination with ONE of the following for treatment of the same indication:

- Anti-interleukin 5 therapy [e.g., Cinqair (reslizumab), Fasenra (benralizumab)]

- Anti-IgE (immunoglobulin E) therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

|                                                          |                                                                 |
|----------------------------------------------------------|-----------------------------------------------------------------|
| Product Name:Nucala auto-injector and pre-filled syringe |                                                                 |
| Diagnosis                                                | Hypereosinophilic Syndrome (HES)                                |
| Approval Length                                          | 12 month(s)                                                     |
| Therapy Stage                                            | Initial Authorization - Transitioning from UHC medical benefits |
| Guideline Type                                           | Prior Authorization                                             |

**Approval Criteria**

**1** - Patient has been established on therapy with Nucala under an active UnitedHealthcare medical benefit prior authorization for the treatment of hypereosinophilic syndrome (HES).

**AND**

**2** - Documentation of positive clinical response to Nucala therapy as demonstrated by at least one of the following

- Reduction in frequency of HES flares
- Maintenance or reduction in background HES therapy requirements

**AND**

**3** - Patient is not receiving Nucala in combination with ONE of the following for treatment of the same indication:

- Anti-interleukin 5 therapy [e.g., Cinqair (reslizumab), Fasenra (benralizumab)]
- Anti-IgE therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor therapy [e.g., Tezspire (tezepelumab)]

**AND**

**4** - Prescribed by ONE of the following:

- Allergist
- Cardiologist
- Hematologist
- Immunologist
- Pulmonologist

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                     |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------|
| Product Name:Nucala auto-injector and pre-filled syringe                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                     |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Hypereosinophilic Syndrome (HES)                                    |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 12 month(s)                                                         |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Initial Authorization – Not transitioning from UHC medical benefits |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Prior Authorization                                                 |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of Hypereosinophilic Syndrome (HES) greater than or equal to 6 months ago</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Both of the following:</p> <p style="padding-left: 20px;"><b>2.1</b> There is no identifiable non-hematologic secondary cause of the patient's HES [e.g., drug hypersensitivity, parasitic helminth infection, HIV (human immunodeficiency virus) infection, non-hematologic malignancy]</p> <p style="text-align: center;"><b>AND</b></p> <p style="padding-left: 20px;"><b>2.2</b> HES is not FIP1L1-PDGFR alpha (gene) kinase-positive</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Submission of medical records (e.g., chart notes, laboratory values, etc.) documenting both of the following:</p> <p style="padding-left: 20px;"><b>3.1</b> Baseline [pre-Nucala (mepolizumab) treatment] blood eosinophil level greater than or equal to 1000 cells/microliter within the past 4 weeks</p> |                                                                     |

**AND**

**3.2** Patient is currently receiving a stable dose of background HES therapy (e.g., oral corticosteroid, immunosuppressor, or cytotoxic therapy)

**AND**

**4** - Patient is not receiving Nucala in combination with ONE of the following for treatment of the same indication:

- Anti-interleukin 5 therapy [e.g., Cinqair (reslizumab), Fasenra (benralizumab)]
- Anti-IgE (immunoglobulin E) therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor therapy [e.g., Tezspire (tezepelumab)]

**AND**

**5** - Prescribed by ONE of the following:

- Allergist
- Cardiologist
- Hematologist
- Immunologist
- Pulmonologist

|                                                                                                                                                                   |                                  |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|
| Product Name:Nucala auto-injector and pre-filled syringe                                                                                                          |                                  |
| Diagnosis                                                                                                                                                         | Hypereosinophilic Syndrome (HES) |
| Approval Length                                                                                                                                                   | 12 month(s)                      |
| Therapy Stage                                                                                                                                                     | Reauthorization                  |
| Guideline Type                                                                                                                                                    | Prior Authorization              |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of positive clinical response to Nucala therapy as demonstrated by at least ONE of the following:</p> |                                  |



**1.1** Reduction in the frequency of Hypereosinophilic Syndrome (HES) flares

**OR**

**1.2** Maintenance or reduction in background HES therapy requirements

**AND**

**2** - Patient is not receiving Nucala in combination with ONE of the following for treatment of the same indication:

- Anti-interleukin 5 therapy [e.g., Cinqair (reslizumab), Fasenra (benralizumab)]
- Anti-IgE (immunoglobulin E) therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor therapy [e.g., Tezspire (tezepelumab)]

|                                                                                                                                                                                                                                                                                                                                                      |                                                                 |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------|
| Product Name:Nucala auto-injector and pre-filled syringe                                                                                                                                                                                                                                                                                             |                                                                 |
| Diagnosis                                                                                                                                                                                                                                                                                                                                            | Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)               |
| Approval Length                                                                                                                                                                                                                                                                                                                                      | 12 month(s)                                                     |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                        | Initial Authorization - Transitioning from UHC medical benefits |
| Guideline Type                                                                                                                                                                                                                                                                                                                                       | Prior Authorization                                             |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Patient has been established on therapy with Nucala under an active UnitedHealthcare medical benefit prior authorization for the treatment of chronic rhinosinusitis with nasal polyps (CRSwNP).</p> <p><b>AND</b></p> <p><b>2</b> - Documentation of positive clinical response to Nucala therapy</p> |                                                                 |

**AND**

**3** - Patient will continue to receive Nucala as add-on maintenance therapy in combination with intranasal corticosteroids (e.g., fluticasone, mometasone, triamcinolone)

**AND**

**4** - Patient is not receiving Nucala in combination with any of the following for treatment of the same indication:

- Anti-interleukin 5 therapy [e.g., Cinqair (reslizumab), Fasenra (benralizumab)]
- Anti-IgE therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor therapy [e.g., Tezspire (tezepelumab)]

**AND**

**5** - Prescribed by ONE of the following

- Allergist
- Immunologist
- Otolaryngologist
- Pulmonologist

**Product Name:**Nucala auto-injector and pre-filled syringe

|                 |                                                                     |
|-----------------|---------------------------------------------------------------------|
| Diagnosis       | Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)                   |
| Approval Length | 12 month(s)                                                         |
| Therapy Stage   | Initial Authorization – Not transitioning from UHC medical benefits |
| Guideline Type  | Prior Authorization                                                 |

### Approval Criteria

**1** - Diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP) defined by ALL of the following:

**1.1** Two or more of the following symptoms for longer than 12 weeks duration:

- Nasal mucopurulent discharge
- Nasal obstruction, blockage, or congestion
- Facial pain, pressure, and/or fullness
- Reduction or loss of sense of smell

**AND**

**1.2** One of the following findings using nasal endoscopy and/or sinus computed tomography (CT):

- Purulent mucus or edema in the middle meatus or ethmoid regions
- Polyps in the nasal cavity or the middle meatus
- Radiographic imaging demonstrating mucosal thickening or partial or complete opacification of paranasal sinuses

**AND**

**1.3** ONE of the following:

- Presence of bilateral nasal polyposis
- Patient has previously required surgical removal of bilateral nasal polyps

**AND**

**1.4** ONE of the following:

**1.4.1** Patient has required prior sinus surgery

**OR**

**1.4.2** Patient has required systemic corticosteroids (e.g., prednisone, methylprednisolone) for CRSwNP in the previous 2 years

**OR**

**1.4.3** Patient has been unable to obtain symptom relief after trial of TWO of the following classes of agents:

- Nasal saline irrigations
- Intranasal corticosteroids (e.g., fluticasone, mometasone, triamcinolone)
- Antileukotriene agents (e.g., montelukast, zafirlukast, zileuton)

**AND**

**2** - Patient will receive Nucala as add-on maintenance therapy in combination with intranasal corticosteroids (e.g., fluticasone, mometasone, triamcinolone).

**AND**

**3** - Patient is not receiving Nucala in combination with ONE of the following for treatment of the same indication:

- Anti-interleukin 5 therapy [e.g., Cinqair (reslizumab), Fasenra (benralizumab)]
- Anti-IgE (immunoglobulin E) therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor therapy [e.g., Tezspire (tezepelumab)]

**AND**

**4** - Prescribed by ONE of the following:

- Allergist
- Immunologist
- Otolaryngologist
- Pulmonologist

|                                                          |                                                   |
|----------------------------------------------------------|---------------------------------------------------|
| Product Name:Nucala auto-injector and pre-filled syringe |                                                   |
| Diagnosis                                                | Chronic Rhinosinusitis with Nasal Polyps (CRSwNP) |
| Approval Length                                          | 12 month(s)                                       |
| Therapy Stage                                            | Reauthorization                                   |
| Guideline Type                                           | Prior Authorization                               |

### Approval Criteria

1 - Documentation of positive clinical response to Nucala therapy

**AND**

2 - Patient will continue to receive Nucala as add-on maintenance therapy in combination with intranasal corticosteroids (e.g., fluticasone, mometasone, triamcinolone)

**AND**

3 - Patient is not receiving Nucala in combination with any of the following for treatment of the same indication:

- Anti-interleukin 5 therapy [e.g., Cinqair (reslizumab), Fasenra (benralizumab)]
- Anti-IgE (immunoglobulin E) therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor therapy [e.g., Tezspire (tezepelumab)]

|                                                                                                                                                                                                                                                         |                                                                 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------|
| Product Name:Nucala auto-injector and pre-filled syringe                                                                                                                                                                                                |                                                                 |
| Diagnosis                                                                                                                                                                                                                                               | Chronic Obstructive Pulmonary Disease (COPD)                    |
| Approval Length                                                                                                                                                                                                                                         | 12 month(s)                                                     |
| Therapy Stage                                                                                                                                                                                                                                           | Initial Authorization - Transitioning from UHC medical benefits |
| Guideline Type                                                                                                                                                                                                                                          | Prior Authorization                                             |
| <p><b>Approval Criteria</b></p> <p>1 - Patient has been established on therapy with Nucala under an active UnitedHealthcare medical benefit prior authorization for the treatment of chronic obstructive pulmonary disease (COPD)</p> <p><b>AND</b></p> |                                                                 |

**2** - Documentation of positive clinical response to Nucala therapy

**AND**

**3** - Patient will continue to receive Nucala as add-on maintenance therapy

**AND**

**4** - Patient is not receiving Nucala in combination with any of the following for treatment of the same indication:

- Anti-interleukin 5 therapy [e.g., Cinqair (reslizumab), Fasenra (benralizumab)]
- Anti-IgE therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

**Product Name:**Nucala auto-injector and pre-filled syringe

|                 |                                                                     |
|-----------------|---------------------------------------------------------------------|
| Diagnosis       | Chronic Obstructive Pulmonary Disease (COPD)                        |
| Approval Length | 12 month(s)                                                         |
| Therapy Stage   | Initial Authorization – Not transitioning from UHC medical benefits |
| Guideline Type  | Prior Authorization                                                 |

### Approval Criteria

**1** - Diagnosis of chronic obstructive pulmonary disease (COPD)

**AND**

**2** - Submission of medical records (e.g., chart notes) documenting all of the following:

- Post-bronchodilator forced expiratory volume (FEV1) / forced vital capacity (FVC) ratio less than 0.7
- Post-bronchodilator FEV1 % predicted greater than or equal to 30% and less than or equal to 70%

- Patient has an eosinophilic phenotype defined by a baseline (pre-mepolizumab treatment) peripheral blood eosinophil level at least 300 cells/microliter

**AND**

**3** - Uncontrolled or inadequately controlled COPD demonstrated by both of the following:

**3.1** ONE of the following:

- Two or more COPD exacerbations in the previous year requiring treatment with systemic corticosteroids and/or antibiotics
- One or more COPD exacerbation(s) that resulted in hospitalization or observation for over 24 hours in an emergency department or urgent care facility in the past year

**AND**

**3.2** COPD exacerbation(s) occurred while receiving maintenance therapy with one of the following:

- Triple therapy with a long-acting muscarinic antagonist (LAMA), long-acting beta agonist (LABA), and inhaled corticosteroid (ICS) (e.g., Breztri Aerosphere, Trelegy Ellipta)
- Dual therapy with a LAMA and LABA (e.g., Anoro Ellipta, Bevespi Aerosphere, Stiolto Respimat) and a failure, contraindication, or intolerance to an ICS

**AND**

**4** - Symptoms of chronic productive cough for at least 3 months in the past year

**AND**

**5** - Nucala will be used as add-on maintenance therapy in combination with one of the following:

- Triple therapy with a long-acting muscarinic antagonist (LAMA), long-acting beta agonist (LABA), and inhaled corticosteroid (ICS) (e.g., Breztri Aerosphere, Trelegy Ellipta)
- Dual therapy with a LAMA and LABA (e.g., Anoro Ellipta, Bevespi Aerosphere, Stiolto Respimat) and a failure, contraindication, or intolerance to an ICS

**AND**

**6** - Patient is not receiving Nucala in combination with any of the following for treatment of the same indication:

- Anti-interleukin 5 therapy [e.g., Cinqair (reslizumab), Fasenra (benralizumab)]
- Anti-IgE (immunoglobulin E) therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

**AND**

**7** - Prescribed by ONE of the following:

- Allergist
- Immunologist
- Pulmonologist

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                              |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------|
| Product Name:Nucala auto-injector and pre-filled syringe                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                              |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Chronic Obstructive Pulmonary Disease (COPD) |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | 12 month(s)                                  |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Reauthorization                              |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Prior Authorization                          |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of positive clinical response to Nucala therapy as demonstrated by at least ONE of the following:</p> <ul style="list-style-type: none"> <li>• Reduction in the frequency of chronic obstructive pulmonary disease (COPD) exacerbations</li> <li>• Increase in percent predicted FEV1 from pretreatment baseline</li> <li>• Reduction in severity or frequency of COPD-related symptoms (e.g., dyspnea, wheezing, cough, sputum volume, decrease in sputum purulence)</li> <li>• Reduction in oral corticosteroid requirements</li> </ul> |                                              |



**AND**

**2** - Nucala is being used as add-on maintenance therapy in combination with one of the following:

- Triple therapy with a long-acting muscarinic antagonist (LAMA), long-acting beta agonist (LABA), and inhaled corticosteroid (ICS) (e.g., Breztri Aerosphere, Trelegy Ellipta)
- Dual therapy with a LAMA and LABA (e.g., Anoro Ellipta, Bevespi Aerosphere, Stiolto Respimat) and a failure, contraindication, or intolerance to an ICS

**AND**

**3** - Patient is not receiving Nucala in combination with any of the following for treatment of the same indication:

- Anti-interleukin 5 therapy [e.g., Cinqair (reslizumab), Fasenra (benralizumab)]
- Anti-IgE (immunoglobulin E) therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

**AND**

**4** - Prescribed by one of the following:

- Allergist
- Immunologist
- Pulmonologist

## 2 . Revision History

| Date      | Notes                                                                                         |
|-----------|-----------------------------------------------------------------------------------------------|
| 9/15/2025 | Updated formularies. Added criteria for COPD. Updated statement on concomitant use throughout |

Nuedexta



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-436482                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Guideline Name</b> | Nuedexta                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Pennsylvania (ACUPA)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 12/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                       |                     |
|-----------------------|---------------------|
| Product Name:Nuedexta |                     |
| Approval Length       | 12 month(s)         |
| Guideline Type        | Prior Authorization |

**Approval Criteria**

1 - Diagnosis of pseudobulbar affect (PBA)

**2 . Revision History**

| Date       | Notes                                                  |
|------------|--------------------------------------------------------|
| 10/31/2025 | Combined formularies. No changes to clinical criteria. |

Nuplazid



## Prior Authorization Guideline

|                       |                                                                                                         |
|-----------------------|---------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-143441                                                                                               |
| <b>Guideline Name</b> | Nuplazid                                                                                                |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>Medicaid - Community &amp; State New Jersey (PSI2300)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 4/1/2024 |
|-----------------|----------|

## 1 . Criteria

|                                                                                                                           |                       |
|---------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Nuplazid*                                                                                                    |                       |
| Approval Length                                                                                                           | 12 month(s)           |
| Therapy Stage                                                                                                             | Initial Authorization |
| Guideline Type                                                                                                            | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of Parkinson's disease</p> <p style="text-align: center;"><b>AND</b></p> |                       |

**2** - Patient is currently experiencing hallucinations and delusions associated with Parkinson's disease psychosis (i.e., hallucination and delusion symptoms started after Parkinson's disease diagnosis)

|       |                                                                                                              |
|-------|--------------------------------------------------------------------------------------------------------------|
| Notes | *NJ Psych Panel Providers (any mental health prescriber) are only subject to initial authorization criteria. |
|-------|--------------------------------------------------------------------------------------------------------------|

Product Name:Nuplazid\*

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                 |
|---------------|-----------------|
| Therapy Stage | Reauthorization |
|---------------|-----------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

### Approval Criteria

**1** - Documentation of positive clinical response to Nuplazid therapy

|       |                                                                                                              |
|-------|--------------------------------------------------------------------------------------------------------------|
| Notes | *NJ Psych Panel Providers (any mental health prescriber) are only subject to initial authorization criteria. |
|-------|--------------------------------------------------------------------------------------------------------------|

## 2 . Revision History

| Date      | Notes                                                               |
|-----------|---------------------------------------------------------------------|
| 2/22/2024 | Updated guideline name to add " ". No changes to clinical criteria. |

Nurtec, Qulipta, Ubrelvy, Zavzpret



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-206564                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Guideline Name</b> | Nurtec, Qulipta, Ubrelvy, Zavzpret                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 4/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                         |                             |
|-------------------------|-----------------------------|
| Product Name:Nurtec ODT |                             |
| Diagnosis               | Acute Treatment of Migraine |
| Approval Length         | 12 month(s)                 |
| Therapy Stage           | Initial Authorization       |
| Guideline Type          | Prior Authorization         |
|                         |                             |

## Approval Criteria

1 - Used for acute treatment of migraine

**AND**

2 - One of the following:

**2.1** Failure (after at least 3 migraine episodes and a minimum of a 30-day trial) to TWO of the following as confirmed by claims history or submission of medical records:

- eletriptan (generic Relpax)
- naratriptan (generic Amerge)
- rizatriptan (generic Maxalt/Maxalt MLT)
- sumatriptan (generic Imitrex)
- zolmitriptan (generic Zomig)

**OR**

**2.2** History of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):

- eletriptan (generic Relpax)
- naratriptan (generic Amerge)
- rizatriptan (generic Maxalt/Maxalt MLT)
- sumatriptan (generic Imitrex)
- zolmitriptan (generic Zomig)

**AND**

3 - One of the following:

**3.1** Patient is currently treated with ONE of the following prophylactic therapies or classes as confirmed by claims history or submission of medical records:

- A beta-blocker (i.e., atenolol, metoprolol, nadolol, propranolol, or timolol)\*
- Candesartan\* (generic Atacand)
- A calcitonin gene-related peptide receptor (CGRP) antagonist or inhibitor for preventive treatment of migraine [i.e., Aimovig, Ajovy\*, Emgality, Qulipta\*, Vyepti\*\*] \*\*\*
- Divalproex sodium (generic Depakote/Depakote ER)
- OnabotulinumtoxinA\*\* (generic Botox)
- A serotonin-norepinephrine reuptake inhibitor [i.e., duloxetine (Cymbalta), venlafaxine (Effexor/Effexor XR)]

- Topiramate (generic Topamax)
- A tricyclic antidepressant [i.e., amitriptyline (Elavil), nortriptyline (Pamelor)]

**OR**

**3.2** Patient has less than 4 migraine days per month

**OR**

**3.3** Patient has greater than or equal to 4 migraine days per month and has contraindication or intolerance to TWO of the following prophylactic therapies or classes (please specify contraindication or intolerance):

- A beta-blocker (i.e., atenolol, metoprolol, nadolol, propranolol, or timolol)\*
- Candesartan\* (generic Atacand)
- A calcitonin gene-related peptide receptor (CGRP) antagonist or inhibitor for preventive treatment of migraine [i.e., Aimovig, Ajovy\*, Emgality, Qulipta\*, Vyepti\*\*] \*\*\*
- Divalproex sodium (generic Depakote/Depakote ER)
- OnabotulinumtoxinA\*\* (generic Botox)
- A serotonin-norepinephrine reuptake inhibitor [i.e., duloxetine (Cymbalta), venlafaxine (Effexor/Effexor XR)]
- Topiramate (generic Topamax)
- A tricyclic antidepressant [i.e., amitriptyline (Elavil), nortriptyline (Pamelor)]

**AND**

**4** - Medication will not be used in combination with another acute calcitonin gene-related peptide receptor (CGRP) antagonists (e.g., Ubrelvy, Zavzpret)

|       |                                                                                                                                                                                                                                                                                                                                |
|-------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Notes | <p>* Timolol, candesartan, Ajovy and Qulipta are non-preferred and should not be included in denial to provider</p> <p>**Vyepti, OnabotulinumtoxinA are medical benefits and should not be included in denial to provider.</p> <p>***CGRP antagonists for preventive treatment of migraines require a prior authorization.</p> |
|-------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                         |                                           |
|-------------------------|-------------------------------------------|
| Product Name:Nurtec ODT |                                           |
| Diagnosis               | Preventive Treatment of Episodic Migraine |
| Approval Length         | 12 month(s)                               |
| Therapy Stage           | Initial Authorization                     |



| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Prior Authorization |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of episodic migraines with greater than or equal to 4 migraine days per month</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Used for preventive treatment of migraines</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - One of the following:</p> <p><b>3.1</b> Failure (after a trial of at least two months), to TWO of the following prophylactic therapies as confirmed by claims history or submission of medical records:</p> <ul style="list-style-type: none"> <li>• A beta-blocker (i.e., atenolol, metoprolol, nadolol, propranolol, or timolol*)</li> <li>• Candesartan* (generic Atacand)</li> <li>• Divalproex sodium (generic Depakote/Depakote ER)</li> <li>• Topiramate (generic Topamax)</li> <li>• A serotonin-norepinephrine reuptake inhibitor [i.e., duloxetine (Cymbalta), venlafaxine (Effexor/Effexor XR)]</li> <li>• A tricyclic antidepressant [i.e., amitriptyline (Elavil), nortriptyline (Pamelor)]</li> </ul> <p style="text-align: center;"><b>OR</b></p> <p><b>3.2</b> History of contraindication or intolerance to TWO of the following prophylactic therapies (please specify contraindication or intolerance):</p> <ul style="list-style-type: none"> <li>• A beta-blocker (i.e., atenolol, metoprolol, nadolol, propranolol, or timolol*)</li> <li>• Candesartan* (generic Atacand)</li> <li>• Divalproex sodium (generic Depakote/Depakote ER)</li> <li>• Topiramate (generic Topamax)</li> <li>• A serotonin-norepinephrine reuptake inhibitor [i.e., duloxetine (Cymbalta), venlafaxine (Effexor/Effexor XR)]</li> <li>• A tricyclic antidepressant [i.e., amitriptyline (Elavil), nortriptyline (Pamelor)]</li> </ul> |                     |

|                                                                                                                                                                                                                          |                                                                                              |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------|
| <b>AND</b>                                                                                                                                                                                                               |                                                                                              |
| <b>4</b> - Medication will not be used in combination with another CGRP (calcitonin gene-related peptide) antagonist or inhibitor used for the preventive treatment of migraines (e.g. Aimovig, Ajovy, Emgality, Vyepti) |                                                                                              |
| Notes                                                                                                                                                                                                                    | * Timolol and candesartan are non-preferred and should not be included in denial to provider |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                        |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------|
| Product Name:Nurtec ODT                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                        |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Acute Treatment of Migraine, Preventive Treatment of Episodic Migraine |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 12 month(s)                                                            |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Reauthorization                                                        |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Prior Authorization                                                    |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of positive clinical response to therapy</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - ONE of the following:</p> <p><b>2.1</b> Medication will not be used in combination with another acute calcitonin gene-related peptide receptor (CGRP) antagonist (e.g., Ubrelvy, Zavzpret)</p> <p style="text-align: center;"><b>OR</b></p> <p><b>2.2</b> Medication will not be used in combination with another CGRP antagonist or inhibitor used for the preventive treatment of migraines (e.g. Aimovig, Ajovy, Emgality, Vyepti)</p> |                                                                        |

|                       |                       |
|-----------------------|-----------------------|
| Product Name:Zavzpret |                       |
| Approval Length       | 12 month(s)           |
| Therapy Stage         | Initial Authorization |

| Guideline Type | Prior Authorization                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                | <p><b>Approval Criteria</b></p> <p><b>1</b> - Used for acute treatment of migraine</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - One of the following:</p> <p><b>2.1</b> Failure (after at least 3 migraine episodes and a minimum of a 30-day trial) to BOTH of the following as confirmed by claims history or submission of medical records:</p> <p><b>2.1.1</b> TWO preferred 5-HT<sub>1</sub> receptor agonist (triptan) alternatives (e.g., sumatriptan, rizatriptan, or naratriptan), one of which must be sumatriptan nasal spray</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2.1.2</b> ONE of the following:</p> <ul style="list-style-type: none"> <li>• Nurtec ODT</li> <li>• Ubrelvy</li> </ul> <p style="text-align: center;"><b>OR</b></p> <p><b>2.2</b> History of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):</p> <ul style="list-style-type: none"> <li>• TWO preferred 5-HT<sub>1</sub> receptor agonist (triptan) alternatives (e.g., sumatriptan, rizatriptan, or naratriptan), one of which must be sumatriptan nasal spray</li> <li>• Nurtec ODT</li> <li>• Ubrelvy</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - One of the following:</p> |

**3.1** Patient is currently treated with ONE of the following prophylactic therapies or classes as confirmed by claims history or submission of medical records:

- A beta-blocker (i.e., atenolol, metoprolol, nadolol, propranolol, or timolol)\*
- Candesartan\* (generic Atacand)
- A calcitonin gene-related peptide receptor (CGRP) antagonist or inhibitor for preventive treatment of migraine [i.e., Aimovig, Ajovy\*, Emgality, Qulipta\*, Vyepti\*\*] \*\*\*
- Divalproex sodium (generic Depakote/Depakote ER)
- OnabotulinumtoxinA\*\* (generic Botox)
- A serotonin-norepinephrine reuptake inhibitor [i.e., duloxetine (Cymbalta), venlafaxine (Effexor/Effexor XR)]
- Topiramate (generic Topamax)
- A tricyclic antidepressant [i.e., amitriptyline (Elavil), nortriptyline (Pamelor)]

**OR**

**3.2** Patient has less than 4 migraine days per month

**OR**

**3.3** Patient has greater than or equal to 4 migraine days per month and has contraindication or intolerance to TWO of the following prophylactic therapies or classes (please specify contraindication or intolerance):

- A beta-blocker (i.e., atenolol, metoprolol, nadolol, propranolol, or timolol)\*
- Candesartan\* (generic Atacand)
- A calcitonin gene-related peptide receptor (CGRP) antagonist or inhibitor for preventive treatment of migraine [i.e., Aimovig, Ajovy\*, Emgality, Qulipta\*, Vyepti\*\*] \*\*\*
- Divalproex sodium (generic Depakote/Depakote ER)
- OnabotulinumtoxinA\*\* (generic Botox)
- A serotonin-norepinephrine reuptake inhibitor [i.e., duloxetine (Cymbalta), venlafaxine (Effexor/Effexor XR)]
- Topiramate (generic Topamax)
- A tricyclic antidepressant [i.e., amitriptyline (Elavil), nortriptyline (Pamelor)]

**AND**

**4** - Medication will not be used in combination with another acute calcitonin gene-related peptide receptor (CGRP) antagonists (e.g., Nurtec ODT, Ubrelvy)

|       |                                                                                                                                                                                                  |
|-------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Notes | <p>* Timolol, candesartan, Ajovy and Qulipta are non-preferred and should not be included in denial to provider</p> <p>**Vyepti, OnabotulinumtoxinA are medical benefits and should not be i</p> |
|-------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|  |                                                                                                                                       |
|--|---------------------------------------------------------------------------------------------------------------------------------------|
|  | <p>ncluded in denial to provider.</p> <p>***CGRP antagonists for preventive treatment of migraines require a prior authorization.</p> |
|--|---------------------------------------------------------------------------------------------------------------------------------------|

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                       |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Ubrelvy                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                       |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Used for acute treatment of migraine</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - One of the following:</p> <p><b>2.1</b> Failure (after at least 3 migraine episodes and a minimum of a 30-day trial) to TWO of the following as confirmed by claims history or submission of medical records:</p> <ul style="list-style-type: none"> <li>• eletriptan (generic Relpax)</li> <li>• naratriptan (generic Amerge)</li> <li>• rizatriptan (generic Maxalt/Maxalt MLT)</li> <li>• sumatriptan (generic Imitrex)</li> <li>• zolmitriptan (generic Zomig)</li> </ul> <p style="text-align: center;"><b>OR</b></p> <p><b>2.2</b> History of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance)</p> <ul style="list-style-type: none"> <li>• eletriptan (generic Relpax)</li> <li>• naratriptan (generic Amerge)</li> <li>• rizatriptan (generic Maxalt/Maxalt MLT)</li> <li>• sumatriptan (generic Imitrex)</li> <li>• zolmitriptan (generic Zomig)</li> </ul> |                       |

**AND**

**3 - One of the following:**

**3.1** Patient is currently treated with ONE of the following prophylactic therapies or classes as confirmed by claims or submission of medical records:

- A beta-blocker (i.e., atenolol, metoprolol, nadolol, propranolol, or timolol)\*
- Candesartan\* (generic Atacand)
- A calcitonin gene-related peptide receptor (CGRP) antagonist or inhibitor for preventive treatment of migraine [i.e., Aimovig, Ajovy\*, Emgality, Qulipta\*, Vyepti\*\*] \*\*\*
- Divalproex sodium (generic Depakote/Depakote ER)
- OnabotulinumtoxinA\*\* (generic Botox)
- A serotonin-norepinephrine reuptake inhibitor [i.e., duloxetine (Cymbalta), venlafaxine (Effexor/Effexor XR)]
- Topiramate (generic Topamax)
- A tricyclic antidepressant [i.e., amitriptyline (Elavil), nortriptyline (Pamelor)]

**OR**

**3.2** Patient has less than 4 migraine days per month

**OR**

**3.3** Patient has greater than or equal to 4 migraine days per month and has contraindication or intolerance to TWO of the following prophylactic therapies or classes (please specify contraindication or intolerance):

- A beta-blocker (i.e., atenolol, metoprolol, nadolol, propranolol, or timolol)\*
- Candesartan\* (generic Atacand)
- A calcitonin gene-related peptide receptor (CGRP) antagonist or inhibitor for preventive treatment of migraine [i.e., Aimovig, Ajovy\*, Emgality, Qulipta\*, Vyepti\*\*] \*\*\*
- Divalproex sodium (generic Depakote/Depakote ER)
- OnabotulinumtoxinA\*\* (generic Botox)
- A serotonin-norepinephrine reuptake inhibitor [i.e., duloxetine (Cymbalta), venlafaxine (Effexor/Effexor XR)]
- Topiramate (generic Topamax)
- A tricyclic antidepressant [i.e., amitriptyline (Elavil), nortriptyline (Pamelor)]

**AND**

|                                                                                                                                                                   |                                                                                                                                                                                                                                                                                                                             |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>4</b> - Medication will not be used in combination with another acute calcitonin gene-related peptide receptor (CGRP) antagonists (e.g., Nurtec ODT, Zavzpret) |                                                                                                                                                                                                                                                                                                                             |
| Notes                                                                                                                                                             | <p>* Timolol, Ajoy, Qulipta and candesartan are non-preferred and should not be included in denial to provider</p> <p>**Vyepi, OnabotulinumtoxinA are medical benefit and should not be included in denial to provider.</p> <p>***CGRP antagonists for preventive treatment of migraines require a prior authorization.</p> |

|                                                                                                                                                                                                                                                                                                        |                     |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Ubrelvy, Zavzpret                                                                                                                                                                                                                                                                         |                     |
| Approval Length                                                                                                                                                                                                                                                                                        | 12 month(s)         |
| Therapy Stage                                                                                                                                                                                                                                                                                          | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                                                                         | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p>1 - Documentation of positive clinical response to therapy</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Medication will not be used in combination with another acute calcitonin gene-related peptide receptor (CGRP) antagonist (e.g., Nurtec ODT)</p> |                     |

|                                                                                                                                                      |                       |
|------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Qulipta                                                                                                                                 |                       |
| Approval Length                                                                                                                                      | 12 month(s)           |
| Therapy Stage                                                                                                                                        | Initial Authorization |
| Guideline Type                                                                                                                                       | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of migraine consistent with The International Classification of Headache Disorders, 3rd edition</p> |                       |

**AND**

**2** - ONE of the following:

**2.1** Patient has 4 to 7 migraine days per month and at least ONE of the following:

**2.1.1** Less than 15 headache days per month

**OR**

**2.1.2** Provider attests this is the member's predominant headache diagnosis (i.e., primary driver of headaches is not different, non-migrainous condition)

**OR**

**2.2** Greater than or equal to 8 migraine days per month

**AND**

**3** - One of the following:

**3.1** Failure (after a trial of at least two months) to TWO of the following prophylactic therapies as confirmed by claims history or submission of medical records:

- A beta-blocker (i.e., atenolol, metoprolol, nadolol, propranolol, or timolol\*)
- Candesartan\* (Atacand)
- Divalproex sodium (Depakote/Depakote ER)
- OnabotulinumtoxinA\*\* (generic Botox)
- A serotonin-norepinephrine reuptake inhibitor [i.e., duloxetine (Cymbalta), venlafaxine (Effexor/Effexor XR)]
- Topiramate (Topamax)
- A tricyclic antidepressant [i.e., amitriptyline (Elavil), nortriptyline (Pamelor)]

**OR**

**3.2** History of contraindication or intolerance to TWO of the following prophylactic therapies (please specify contraindication or intolerance):



- A beta-blocker (i.e., atenolol, metoprolol, nadolol, propranolol, or timolol\*)
- Candesartan\* (Atacand)
- Divalproex sodium (Depakote/Depakote ER)
- OnabotulinumtoxinA\*\* (generic Botox)
- A serotonin-norepinephrine reuptake inhibitor [i.e., duloxetine (Cymbalta), venlafaxine (Effexor/Effexor XR)]
- Topiramate (Topamax)
- A tricyclic antidepressant [i.e., amitriptyline (Elavil), nortriptyline (Pamelor)]

**AND**

**4** - One of the following:

**4.1** Failure (after a trial of at least three months) to Nurtec ODT as confirmed by claims history or submission of medical records

**OR**

**4.2** History of contraindication or intolerance to Nurtec ODT (please specify contraindication or intolerance)

**AND**

**5** - Medication will not be used in combination with another CGRP antagonist or inhibitor used for the preventive treatment of migraines (e.g. Aimovig, Ajovy, Emgality, Nurtec ODT, Vyepti)

Notes

\* Timolol, candesartan are non-preferred and should not be included in denial to provider

\*\*OnabotulinumtoxinA is a medical benefit and should not be included in denial to provider.

Product Name: Qulipta

Approval Length 12 month(s)

Therapy Stage Reauthorization

Guideline Type Prior Authorization

**Approval Criteria**

1 - Documentation of positive clinical response to therapy

**AND**

2 - Medication will not be used in combination with another CGRP antagonist or inhibitor used for the preventive treatment of migraines (e.g., Aimovig, Ajovy, Emgality, Nurtec ODT, Vyepti)

## 2 . Background

### Benefit/Coverage/Program Information

#### PDL Links:

CO: <https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html>

HI: <https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html>

NJ: <https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html>

NM: <https://www.uhcprovider.com/en/health-plans-by-state/new-mexico-health-plans/nm-comm-plan-home/nm-cp-pharmacy.html>

NY: <https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html>

PA: <https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP>

RI: <https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html>

## 3 . Revision History

| Date     | Notes                                                                                                                                                                                          |
|----------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 3/3/2025 | Updated formularies. Added eletriptan and zolmitriptan as step therapy option. Updated prophylactic therapy requirement contraindication /intolerance count from all to two. Updated PDL links |

Nuzyra



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-231196                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Guideline Name</b> | Nuzyra                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State Michigan (ACUMI)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 5/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                             |                     |
|-----------------------------|---------------------|
| Product Name:Nuzyra tablets |                     |
| Guideline Type              | Prior Authorization |

### **Approval Criteria**

**1** - For continuation of therapy upon hospital discharge

**OR**

**2** - As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication

**OR**

**3** - ALL of the following:

**3.1** Diagnosis of community-acquired bacterial pneumonia (CABP)

**AND**

**3.2** Infection caused by an organism that is confirmed to be or likely to be susceptible to treatment with Nuzyra

**AND**

**3.3** ONE of the following:

**3.3.1** Failure to THREE of the following antibiotics or antibiotic regimens, as confirmed by claims history or submission of medical records:

- Amoxicillin
- A macrolide
- Doxycycline
- A fluoroquinolone
- Combination therapy with amoxicillin/clavulanate or cephalosporin AND a macrolide or doxycycline

**OR**

**3.3.2** History of intolerance or contraindication to ALL of the following antibiotics or antibiotic regimens (please specify intolerance or contraindication):

- Amoxicillin
- A macrolide
- Doxycycline
- A fluoroquinolone
- Combination therapy with amoxicillin/clavulanate or cephalosporin AND a macrolide or doxycycline

**OR**

**4** - ALL of the following:

**4.1** ONE of the following diagnoses:

**4.1.1** BOTH of the following:

**4.1.1.1** Acute bacterial skin and skin structure infections

**AND**

**4.1.1.2** Infection caused by methicillin-resistant *Staphylococcus aureus* (MRSA) documented by culture and sensitivity report

**OR**

**4.1.2** BOTH of the following:

**4.1.2.1** Empirical treatment of a patient with acute bacterial skin and skin structure infections

**AND**

**4.1.2.2** Presence of MRSA infection is likely

**AND**

**4.2** ONE of the following:

**4.2.1** Failure to linezolid (generic Zyvox) as confirmed by claims history or submission medical records

**OR**

**4.2.2** History of intolerance or contraindication to linezolid (generic Zyvox) (please specify intolerance or contraindication)

**AND**

**4.3** ONE of the following:

**4.3.1** Failure to ONE of the following antibiotics as confirmed by claims history or submission medical records:

- Sulfamethoxazole-trimethoprim (SMZ-TMP)
- A tetracycline
- Clindamycin

**OR**

**4.3.2** History of intolerance or contraindication to ALL of the following antibiotics (please specify intolerance or contraindication):

- Sulfamethoxazole-trimethoprim (SMZ-TMP)
- A tetracycline
- Clindamycin

**OR**

**5** - ALL of the following:

**5.1** Diagnosis of acute bacterial skin and skin structure infections

**AND**

**5.2** Infection caused by an organism that is confirmed to be or likely to be susceptible to treatment with Nuzyra

**AND**

**5.3** ONE of the following:

**5.3.1** Failure to THREE of the following antibiotics confirmed by claims history or submission medical records:

- A penicillin
- A cephalosporin
- A tetracycline
- Sulfamethoxazole-trimethoprim (SMZ-TMP)
- Clindamycin

**OR**

**5.3.2** History of intolerance or contraindication to ALL of the following antibiotics (please specify intolerance or contraindication):

- A penicillin
- A cephalosporin
- A tetracycline
- Sulfamethoxazole-trimethoprim (SMZ-TMP)
- Clindamycin

**OR**

**6** - The drug has been recognized for treatment of the indication by the Infectious Diseases Society of America (IDSA)

|       |                                                                                                                                                                                                                                                                     |
|-------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Notes | Authorization duration for CABP and acute bacterial skin and skin structure infections will be issued for up to 14 days. For all IDSA recognized indications, authorization duration is based on provider and IDSA recommended treatment durations, up to 6 months. |
|-------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

## 2 . Revision History

| Date      | Notes                                                          |
|-----------|----------------------------------------------------------------|
| 3/26/2025 | Combined formularies. Clarified submission of medical records. |





OAB Agents



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-231199                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Guideline Name</b> | OAB Agents                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 5/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                                     |              |
|-------------------------------------|--------------|
| Product Name:generic tolterodine IR |              |
| Approval Length                     | 12 month(s)  |
| Guideline Type                      | Step Therapy |
| Approval Criteria                   |              |

**1** - Failure to treatment with oxybutynin immediate release as confirmed by claims history or submission of medical records

**OR**

**2** - History of contraindication or intolerance to oxybutynin immediate release (please specify contraindication or intolerance)

**Product Name:**generic tolterodine ER

**Approval Length** 12 month(s)

**Guideline Type** Step Therapy

**Approval Criteria**

**1** - Failure to treatment with oxybutynin extended-release as confirmed by claims history or submission of medical records

**OR**

**2** - History of contraindication or intolerance to oxybutynin extended-release (please specify contraindication or intolerance)

**Product Name:**Brand Detrol LA, Brand Ditropan XL, darifenacin ER, Gelnique, Gemtesa, trospium ER, Brand Vesicare

**Approval Length** 12 month(s)

**Guideline Type** Prior Authorization

**Approval Criteria**

**1** - Failure to a trial of THREE of the following confirmed by claims history or submission of medical records:

- oxybutynin extended-release tablet (generic Ditropan XL)
- tolterodine extended-release capsule (generic Detrol LA)

- trospium tablet
- solifenacin tablet (generic Vesicare)

**OR**

**2** - History of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):

- oxybutynin extended-release tablet (generic Ditropan XL)
- tolterodine extended-release capsule (generic Detrol LA)
- trospium tablet
- solifenacin tablet (generic Vesicare)

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                     |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name: Oxytrol (Rx)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                     |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 12 month(s)         |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Failure to a trial of THREE of the following, confirmed by claims history or submission of medical records:</p> <ul style="list-style-type: none"> <li>• Oxytrol for Women (oxybutynin OTC) patch</li> <li>• tolterodine immediate release (generic Detrol) or tolterodine extended-release capsule (generic Detrol LA)</li> <li>• trospium tablet</li> <li>• solifenacin tablet (generic Vesicare)</li> </ul> <p><b>OR</b></p> <p><b>2</b> - History of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):</p> <ul style="list-style-type: none"> <li>• Oxytrol for Women (oxybutynin OTC) patch</li> <li>• tolterodine immediate release (generic Detrol) or tolterodine extended-release capsule (generic Detrol LA)</li> <li>• trospium tablet</li> <li>• solifenacin tablet (generic Vesicare)</li> </ul> |                     |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                     |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:flavoxate, oxybutynin oral solution, Brand Detrol                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                     |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 12 month(s)         |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Failure to a trial of ALL of the following, confirmed by claims history or submission of medical records:</p> <ul style="list-style-type: none"> <li>• oxybutynin syrup or tablet</li> <li>• tolterodine tablet (generic Detrol)</li> <li>• trospium tablet</li> </ul> <p style="text-align: center;"><b>OR</b></p> <p><b>2</b> - History of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):</p> <ul style="list-style-type: none"> <li>• oxybutynin syrup or tablet</li> <li>• tolterodine tablet (generic Detrol)</li> <li>• trospium tablet</li> </ul> |                     |

|                                                                                                                                                                                                                  |                     |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Vesicare LS                                                                                                                                                                                         |                     |
| Approval Length                                                                                                                                                                                                  | 12 month(s)         |
| Guideline Type                                                                                                                                                                                                   | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of neurogenic detrusor overactivity (NDO) (neurogenic bladder)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - ONE of the following:</p> |                     |

**2.1** Failure to a trial of ONE of the following, as confirmed by claims history or submission of medical records:

- oxybutynin syrup
- oxybutynin tablet
- oxybutynin extended release tablet (generic Ditropan XL)

**OR**

**2.2** History of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):

- oxybutynin syrup
- oxybutynin tablet
- oxybutynin extended release tablet (generic Ditropan XL)

Product Name: Brand Myrbetriq tabs, generic mirabegron tabs, generic fesoterodine ER, Brand Toviaz

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

**1** - BOTH of the following:

**1.1** Diagnosis of overactive bladder (OAB)

**AND**

**1.2** ONE of the following:

**1.2.1** Failure to a trial of THREE of the following confirmed by claims history or submission of medical records:

- oxybutynin extended-release tablet (generic Ditropan XL)
- tolterodine immediate release (generic Detrol) or tolterodine extended-release capsule (generic Detrol LA)
- trospium tablet

- solifenacin tablet (generic Vesicare)

**OR**

**1.2.2** History of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):

- oxybutynin extended-release tablet (generic Ditropan XL)
- tolterodine immediate release (generic Detrol) or tolterodine extended-release capsule (generic Detrol LA)
- trospium tablet
- solifenacin tablet (generic Vesicare)

**OR**

**2** - BOTH of the following:

**2.1** Diagnosis of neurogenic detrusor overactivity (NDO) (neurogenic bladder)

**AND**

**2.2** ONE of the following:

**2.2.1** Failure to a trial of ONE of the following, as confirmed by claims history or submission of medical records:

- oxybutynin syrup
- oxybutynin tablet
- oxybutynin extended release tablet (generic Ditropan XL)

**OR**

**2.2.2** History of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):

- oxybutynin syrup
- oxybutynin tablet
- oxybutynin extended release tablet (generic Ditropan XL)

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                     |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name: Myrbetriq granules                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                     |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 12 month(s)         |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1 - Diagnosis of neurogenic detrusor overactivity (NDO) (neurogenic bladder)</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>2 - ONE of the following:</b></p> <p><b>2.1</b> Failure to a trial of ONE of the following, as confirmed by claims history or submission of medical records:</p> <ul style="list-style-type: none"> <li>• oxybutynin syrup</li> <li>• oxybutynin tablet</li> <li>• oxybutynin extended release tablet (generic Ditropan XL)</li> </ul> <p style="text-align: center;"><b>OR</b></p> <p><b>2.2</b> History of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):</p> <ul style="list-style-type: none"> <li>• oxybutynin syrup</li> <li>• oxybutynin tablet</li> <li>• oxybutynin extended release tablet (generic Ditropan XL)</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>3 - ONE of the following:</b></p> <p><b>3.1</b> Patient is 3 years of age to (including) 17 years of age</p> <p style="text-align: center;"><b>OR</b></p> <p><b>3.2</b> BOTH of the following:</p> |                     |



**3.2.1** Physician has provided rationale for needing to use this medication in an unapproved age range

**AND**

**3.2.2** The use of this medication for a patient outside the FDA (Food and Drug Administration) approved age range is supported by information from ONE of the following appropriate compendia:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopoeia - National Formulary (USP-NF)

## 2 . Revision History

| Date      | Notes                                                 |
|-----------|-------------------------------------------------------|
| 3/27/2025 | Combined formularies. No update to clinical criteria. |

Ocaliva



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-164691                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Guideline Name</b> | Ocaliva                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State Michigan (ACUMI)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 3/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                      |                       |
|----------------------|-----------------------|
| Product Name:Ocaliva |                       |
| Approval Length      | 12 month(s)           |
| Therapy Stage        | Initial Authorization |
| Guideline Type       | Prior Authorization   |

**Approval Criteria**

**1** - Diagnosis of primary biliary cholangitis

**AND**

**2** - ONE of the following:

- Patient does not have cirrhosis
- Patient has compensated cirrhosis without evidence of portal hypertension

**AND**

**3** - ONE of the following:

**3.1** BOTH of the following:

- Used in combination with ursodeoxycholic acid (e.g., Urso, ursodiol)
- Patient has failed to achieve an alkaline phosphatase (ALP) level of less than 1.67 times the upper limit of normal after at least 12 consecutive months of treatment with ursodeoxycholic acid (e.g., Urso, ursodiol)

**OR**

**3.2** History of contraindication or intolerance to ursodeoxycholic acid (e.g., Urso, ursodiol) (please specify contraindication or intolerance)

**AND**

**4** - Patient is not receiving Ocaliva in combination with Iqirvo (elafibranor) or Livdelzi (seladelpar)

**AND**

**5** - Prescribed by ONE of the following:

- Hepatologist
- Gastroenterologist

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                     |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Ocaliva                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                     |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 12 month(s)         |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Submission of medical records (e.g., laboratory values) documenting a reduction in alkaline phosphatase (ALP) level from pre-treatment baseline (i.e., prior to Ocaliva therapy)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - ONE of the following:</p> <ul style="list-style-type: none"> <li>• Patient does not have cirrhosis</li> <li>• Patient has compensated cirrhosis without evidence of portal hypertension</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Patient is not receiving Ocaliva in combination with Iqirvo (elafibranor) or Livdelzi (seladelpar)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>4</b> - Prescribed by ONE of the following:</p> <ul style="list-style-type: none"> <li>• Hepatologist</li> <li>• Gastroenterologist</li> </ul> |                     |

## 2 . Revision History

| Date     | Notes                                                                        |
|----------|------------------------------------------------------------------------------|
| 2/4/2025 | Updated formularies. Minor formatting changes. Added concurrent use criteria |

Odomzo



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-160617                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Guideline Name</b> | Odomzo                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 1/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                     |                       |
|---------------------|-----------------------|
| Product Name:Odomzo |                       |
| Diagnosis           | Basal Cell Carcinoma  |
| Approval Length     | 12 month(s)           |
| Therapy Stage       | Initial Authorization |
| Guideline Type      | Prior Authorization   |

### Approval Criteria

1 - Diagnosis of nodal metastatic basal cell carcinoma (BCC)

**OR**

2 - Diagnosis of diffuse basal cell carcinoma (BCC) formation (e.g., Gorlin syndrome, other genetic forms of multiple BCC)

**OR**

3 - BOTH of the following:

3.1 Diagnosis of locally advanced basal cell carcinoma

**AND**

3.2 ONE of the following:

- Cancer has recurred following surgery
- Cancer has recurred following radiation
- Patient is not a candidate for surgery
- Patient is not a candidate for radiation

|                      |                      |
|----------------------|----------------------|
| Product Name: Odomzo |                      |
| Diagnosis            | Basal Cell Carcinoma |
| Approval Length      | 12 month(s)          |
| Therapy Stage        | Reauthorization      |
| Guideline Type       | Prior Authorization  |
| Approval Criteria    |                      |

1 - Patient does not show evidence of progressive disease while on Odomzo therapy

| Product Name:Odomzo                                                                                                                     |                           |
|-----------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Diagnosis                                                                                                                               | NCCN Recommended Regimens |
| Approval Length                                                                                                                         | 12 month(s)               |
| Therapy Stage                                                                                                                           | Initial Authorization     |
| Guideline Type                                                                                                                          | Prior Authorization       |
| <b>Approval Criteria</b><br><br>1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium |                           |

| Product Name:Odomzo                                                                               |                           |
|---------------------------------------------------------------------------------------------------|---------------------------|
| Diagnosis                                                                                         | NCCN Recommended Regimens |
| Approval Length                                                                                   | 12 month(s)               |
| Therapy Stage                                                                                     | Reauthorization           |
| Guideline Type                                                                                    | Prior Authorization       |
| <b>Approval Criteria</b><br><br>1 - Documentation of positive clinical response to Odomzo therapy |                           |

## 2 . Revision History

| Date       | Notes                                                                                                                                                          |
|------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 11/13/2024 | Updated criteria per NCCN recommendations to reflect that Odomzo is recommended for basal cell carcinoma with nodal metastases but not with distant metastases |



Ogsiveo



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-186193                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Guideline Name</b> | Ogsiveo                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Washington (ACUWA, ACUWAAHE, ACUWAC)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 4/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                      |                |
|----------------------|----------------|
| Product Name:Ogsiveo |                |
| Diagnosis            | Desmoid Tumors |
| Approval Length      | 12 month(s)    |

|                                                                                                                                                                                                                                                                  |                       |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                                                                                                                                                                                                    | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                   | Prior Authorization   |
| <b>Approval Criteria</b><br><br><b>1</b> - Diagnosis of desmoid tumor<br><br><p style="text-align: center;"><b>AND</b></p> <b>2</b> - Disease is progressive<br><br><p style="text-align: center;"><b>AND</b></p> <b>3</b> - Patient requires systemic treatment |                       |

|                                                                                                                           |                     |
|---------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Ogsiveo                                                                                                      |                     |
| Diagnosis                                                                                                                 | Desmoid Tumors      |
| Approval Length                                                                                                           | 12 month(s)         |
| Therapy Stage                                                                                                             | Reauthorization     |
| Guideline Type                                                                                                            | Prior Authorization |
| <b>Approval Criteria</b><br><br><b>1</b> - Patient does not show evidence of progressive disease while on Ogsiveo therapy |                     |

|                      |                           |
|----------------------|---------------------------|
| Product Name:Ogsiveo |                           |
| Diagnosis            | NCCN Recommended Regimens |
| Approval Length      | 12 month(s)               |
| Therapy Stage        | Initial Authorization     |
| Guideline Type       | Prior Authorization       |

**Approval Criteria**

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Ogsiveo

|           |                           |
|-----------|---------------------------|
| Diagnosis | NCCN Recommended Regimens |
|-----------|---------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                 |
|---------------|-----------------|
| Therapy Stage | Reauthorization |
|---------------|-----------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

1 - Documentation of positive clinical response to Ogsiveo therapy

## 2 . Revision History

| Date      | Notes                                                                                                                             |
|-----------|-----------------------------------------------------------------------------------------------------------------------------------|
| 2/21/2025 | Combined formularies. Added new GPIs for Ogsiveo (IN previously al ready had new GPIs included). No changes to clinical criteria. |

Ohtuvayre



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-435233                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Guideline Name</b> | Ohtuvayre                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Washington (ACUWA, ACUWAAHE, ACUWAC)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 12/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                        |                       |
|------------------------|-----------------------|
| Product Name:Ohtuvayre |                       |
| Approval Length        | 12 month(s)           |
| Therapy Stage          | Initial Authorization |
| Guideline Type         | Prior Authorization   |

**Approval Criteria**

**1** - Diagnosis of chronic obstructive pulmonary disease (COPD)

**AND**

**2** - Submission of medical records (e.g., chart notes) documenting BOTH of the following:

**2.1** Post-bronchodilator forced expiratory volume (FEV1) / forced vital capacity (FVC) ratio less than 0.7

**AND**

**2.2** Post-bronchodilator FEV1 % predicted greater than or equal to 30% and less than 80%

**AND**

**3** - BOTH of the following:

**3.1** ONE of the following:

**3.1.1** FEV1 is less than 80% of predicted but greater than or equal to 50% of predicted

**OR**

**3.1.2** ALL of the following:

**3.1.2.1** FEV1 less than 50% of predicted

**AND**

**3.1.2.2** History of chronic bronchitis

**AND**

**3.1.2.3 ONE of the following:**

- Failure to a selective phosphodiesterase 4 (PDE4) inhibitor [i.e., roflumilast (Daliresp)] as confirmed by claims history or submission of medical record
- History of contraindication or intolerance to a selective phosphodiesterase 4 (PDE4) inhibitor [i.e., roflumilast (Daliresp)] (please specify contraindication or intolerance)

**AND**

**3.2 ONE of the following:**

**3.2.1** Patient is on a stabilized dose and receiving concomitant therapy with ONE of the following as confirmed by claims history or submission of medical records:

- A long-acting beta-agonist [LABA (e.g., Serevent Diskus)]
- A long-acting antimuscarinic agent [LAMA (e.g., Spiriva Respimat/HandiHaler)]
- A LABA/LAMA (e.g., Anoro Ellipta, Bevespi Aerosphere, Stiolto Respimat)
- An ISC/LABA/LAMA (i.e., Breztri Aerosphere, Trelegy Ellipta)

**OR**

**3.2.2** Patient has a failure to ALL of the following as confirmed by claims history or submission of medical records:

- A long-acting beta-agonist [LABA (e.g., Serevent Diskus)]
- A long-acting antimuscarinic agent [LAMA (e.g., Spiriva Respimat/HandiHaler)]
- A LABA/LAMA (e.g., Anoro Ellipta, Bevespi Aerosphere, Stiolto Respimat)
- An ISC/LABA/LAMA (i.e., Breztri Aerosphere, Trelegy Ellipta)

**OR**

**3.2.3** Patient has a contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):

- A long-acting beta-agonist [LABA (e.g., Serevent Diskus)]
- A long-acting antimuscarinic agent [LAMA (e.g., Spiriva Respimat/HandiHaler)]
- A LABA/LAMA (e.g., Anoro Ellipta, Bevespi Aerosphere, Stiolto Respimat)
- An ISC/LABA/LAMA (i.e., Breztri Aerosphere, Trelegy Ellipta)

**OR**

**3.2.4 BOTH of the following:**

**3.2.4.1** Patient is unable to use a metered-dose, dry powder or slow mist inhaler (e.g. Spiriva RespiMat) to control their COPD due to ONE of the following:

- Cognitive or physical impairment limiting coordination of handheld devices (e.g., cognitive decline, arthritis in the hands) (Document impairment)
- Patient is unable to generate adequate inspiratory force (e.g., peak inspiratory flow rate (PIFR) resistance is less than 60 liters per minute))

**AND**

**3.2.4.2** Patient requires the use of BOTH of the following as confirmed by claims history or submission of medical records:

- A nebulized LABA [i.e., arformoterol (generic Brovana), formoterol (generic Perforomist)]
- A nebulized long-acting antimuscarinic agent [LAMA (i.e., Yupelri)]

**AND**

**4** - Patient experiences dyspnea during everyday activities (e.g., short of breath when walking up a slight hill)

**AND**

**5** - Prescribed by or in consultation with a Pulmonologist

|                        |                     |
|------------------------|---------------------|
| Product Name:Ohtuvayre |                     |
| Approval Length        | 12 month(s)         |
| Therapy Stage          | Reauthorization     |
| Guideline Type         | Prior Authorization |
| Approval Criteria      |                     |

**1** - Documentation of positive clinical response to Ohtuvayre therapy demonstrated by BOTH of the following:

**1.1** Improved COPD (chronic obstructive pulmonary disease) symptoms (e.g., dyspnea)

**AND**

**1.2** Improved FEV1 (forced expiratory volume)

## **2 . Revision History**

| Date      | Notes                                                                          |
|-----------|--------------------------------------------------------------------------------|
| 11/3/2025 | Combined formularies. No changes to clinical criteria. Minor cosmetic updates. |



Ojemda



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-356195                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Guideline Name</b> | Ojemda                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Washington (ACUWA, ACUWAAHE, ACUWAC)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 9/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                     |                            |
|---------------------|----------------------------|
| Product Name:Ojemda |                            |
| Diagnosis           | Pediatric Low-Grade Glioma |
| Approval Length     | 12 month(s)                |

|                                                                                                                                                                                                                                                                                                                                                                                                           |                       |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                             | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                            | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of pediatric low-grade glioma</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Disease is relapsed or refractory</p> <p style="text-align: center;"><b>AND</b></p> <p>3 - Presence of ONE of the following genetic mutations:</p> <ul style="list-style-type: none"> <li>• BRAF fusion or rearrangement</li> <li>• BRAF V600 mutation</li> </ul> |                       |

|                                                                                                                          |                            |
|--------------------------------------------------------------------------------------------------------------------------|----------------------------|
| Product Name:Ojemda                                                                                                      |                            |
| Diagnosis                                                                                                                | Pediatric Low-Grade Glioma |
| Approval Length                                                                                                          | 12 month(s)                |
| Therapy Stage                                                                                                            | Reauthorization            |
| Guideline Type                                                                                                           | Prior Authorization        |
| <p><b>Approval Criteria</b></p> <p>1 - Patient does not show evidence of progressive disease while on Ojemda therapy</p> |                            |

|                     |                           |
|---------------------|---------------------------|
| Product Name:Ojemda |                           |
| Diagnosis           | NCCN Recommended Regimens |
| Approval Length     | 12 month(s)               |

|                                                                                                                                                |                       |
|------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                                                                                  | Initial Authorization |
| Guideline Type                                                                                                                                 | Prior Authorization   |
| <b>Approval Criteria</b><br><br><b>1</b> - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium |                       |

|                                                                                                          |                           |
|----------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Ojemda                                                                                      |                           |
| Diagnosis                                                                                                | NCCN Recommended Regimens |
| Approval Length                                                                                          | 12 month(s)               |
| Therapy Stage                                                                                            | Reauthorization           |
| Guideline Type                                                                                           | Prior Authorization       |
| <b>Approval Criteria</b><br><br><b>1</b> - Documentation of positive clinical response to Ojemda therapy |                           |

## 2 . Revision History

| Date     | Notes                                                                                                                            |
|----------|----------------------------------------------------------------------------------------------------------------------------------|
| 8/1/2025 | Combined formularies. Updated verbiage in NCCN initial auth section, with no changes to clinical intent. Minor cosmetic updates. |

Ojjaara



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-164101                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Guideline Name</b> | Ojjaara                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 2/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                      |                       |
|----------------------|-----------------------|
| Product Name:Ojjaara |                       |
| Approval Length      | 6 month(s)            |
| Therapy Stage        | Initial Authorization |
| Guideline Type       | Prior Authorization   |
|                      |                       |

## **Approval Criteria**

**1** - Diagnosis of symptomatic lower-risk myelofibrosis

**OR**

**2** - All of the following:

**2.1** Diagnosis of higher-risk myelofibrosis

**AND**

**2.2** Presence of symptomatic splenomegaly and/or constitutional symptoms

**AND**

**2.3** One of the following:

- Used as continued therapy near the start of conditioning therapy in a transplant candidate
- Patient is not a transplant candidate or transplant not currently feasible

**OR**

**3** - Diagnosis of myelofibrosis-associated anemia

**OR**

**4** - Both of the following:

**4.1** Diagnosis of accelerated/blast phase myeloproliferative neoplasm

**AND**

**4.2** One of the following:

- Used for the improvement of splenomegaly or other disease-related symptoms

- Continued treatment as a single agent near to the start of conditioning therapy in transplant candidates for the improvement of splenomegaly and other disease-related symptoms

|                                                                                                                                                           |                                                                                                                                                                                                                           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Product Name:Ojjaara                                                                                                                                      |                                                                                                                                                                                                                           |
| Approval Length                                                                                                                                           | 6 month(s)                                                                                                                                                                                                                |
| Therapy Stage                                                                                                                                             | Reauthorization                                                                                                                                                                                                           |
| Guideline Type                                                                                                                                            | Prior Authorization                                                                                                                                                                                                       |
| <b>Approval Criteria</b><br><br><b>1</b> - Documentation that patient has evidence of symptom improvement or reduction in spleen volume while on Ojjaara* |                                                                                                                                                                                                                           |
| Notes                                                                                                                                                     | *If documentation does not provide evidence of symptom improvement or reduction in spleen volume while on Ojjaara, authorization will be issued for 2 months to allow for dose titration with discontinuation of therapy. |

|                                                                                                                                                |                           |
|------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Ojjaara                                                                                                                           |                           |
| Diagnosis                                                                                                                                      | NCCN Recommended Regimens |
| Approval Length                                                                                                                                | 12 month(s)               |
| Therapy Stage                                                                                                                                  | Initial Authorization     |
| Guideline Type                                                                                                                                 | Prior Authorization       |
| <b>Approval Criteria</b><br><br><b>1</b> - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium |                           |

|                      |                           |
|----------------------|---------------------------|
| Product Name:Ojjaara |                           |
| Diagnosis            | NCCN Recommended Regimens |
| Approval Length      | 12 month(s)               |
| Therapy Stage        | Reauthorization           |

|                                                                                                           |                     |
|-----------------------------------------------------------------------------------------------------------|---------------------|
| Guideline Type                                                                                            | Prior Authorization |
| <b>Approval Criteria</b><br><br><b>1</b> - Documentation of positive clinical response to Ojjaara therapy |                     |

## 2 . Revision History

| Date      | Notes                      |
|-----------|----------------------------|
| 1/22/2025 | Updated clinical criteria. |

Olumiant



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-435227                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Guideline Name</b> | Olumiant                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 12/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                        |                           |
|------------------------|---------------------------|
| Product Name: Olumiant |                           |
| Diagnosis              | Rheumatoid Arthritis (RA) |
| Approval Length        | 12 month(s)               |
| Therapy Stage          | Initial Authorization     |
| Guideline Type         | Prior Authorization       |
| Approval Criteria      |                           |



**1 - Diagnosis of moderately to severely active rheumatoid arthritis (RA)**

**AND**

**2 - Patient is not receiving Olumiant in combination with any of the following:**

- Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Rinvoq (upadacitinib)]
- Potent immunosuppressant (e.g., azathioprine or cyclosporine)

**AND**

**3 - Prescribed by or in consultation with a rheumatologist**

**AND**

**4 - ONE of the following:**

**4.1 Patient is currently on Olumiant therapy as confirmed by claims history or submission of medical records**

**OR**

**4.2 BOTH of the following:**

**4.2.1 ONE of the following:**

- Failure to a 3 month trial of ONE non-biologic disease modifying anti-rheumatic drug (DMARD) [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine] at maximally indicated doses as confirmed by claims history or submission of medical records
- History of contraindication or intolerance to ONE non-biologic DMARD [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine] (please specify contraindication or intolerance)
- Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of rheumatoid arthritis as confirmed by claims history or submission of medical records [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi

(golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Rinvoq (upadacitinib)]

**AND**

**4.2.2 ONE of the following:**

- Failure to at least ONE TNF (tumor necrosis factor) antagonist therapy as confirmed by claims history or submission of medical records
- History of intolerance or contraindication to at least ONE TNF antagonist therapy (please specify intolerance or contraindication)
- Patient has a documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-V-TR 300.29 for specific phobia diagnostic criteria)

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Olumiant                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                           |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Rheumatoid Arthritis (RA) |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 12 month(s)               |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Reauthorization           |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Prior Authorization       |
| <p><b>Approval Criteria</b></p> <p><b>1 - Documentation of positive clinical response to Olumiant therapy</b></p> <p><b>AND</b></p> <p><b>2 - Patient is not receiving Olumiant in combination with any of the following:</b></p> <ul style="list-style-type: none"> <li>• Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Rinvoq (upadacitinib)]</li> <li>• Potent immunosuppressant (e.g., azathioprine or cyclosporine)</li> </ul> |                           |

|                       |
|-----------------------|
| Product Name:Olumiant |
|-----------------------|

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                       |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Alopecia Areata       |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1 - Diagnosis of severe alopecia areata</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>2 - Other causes of hair loss have been ruled out (e.g., androgenetic alopecia, cicatricial alopecia, secondary syphilis, tinea capitis, triangular alopecia, and trichotillomania)</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>3 - Patient requesting therapy for current episode of alopecia areata</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>4 - Patient is not receiving Olumiant in combination with any of the following:</b></p> <ul style="list-style-type: none"> <li>Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Rinvoq (upadacitinib), Litfulo (ritlecinib)]</li> <li>Potent immunosuppressant (e.g., azathioprine or cyclosporine)</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>5 - Prescribed by or in consultation with a dermatologist</b></p> |                       |

|                        |                 |
|------------------------|-----------------|
| Product Name: Olumiant |                 |
| Diagnosis              | Alopecia Areata |
| Approval Length        | 12 month(s)     |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                     |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p>1 - Documentation of positive clinical response to Olumiant therapy</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Patient is not receiving Olumiant in combination with any of the following:</p> <ul style="list-style-type: none"> <li>Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Rinvoq (upadacitinib), Litfulo (ritlecitinib)]</li> <li>Potent immunosuppressant (e.g., azathioprine or cyclosporine)</li> </ul> |                     |

## 2 . Revision History

| Date       | Notes                                                                                                                                       |
|------------|---------------------------------------------------------------------------------------------------------------------------------------------|
| 10/30/2025 | Removed criteria requiring a minimum of 50% scalp hair loss with current episode lasting six months under initial auth for alopecia areata. |

Omega



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-242210                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Guideline Name</b> | Omega                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 6/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                                                                                                       |                             |
|-------------------------------------------------------------------------------------------------------|-----------------------------|
| Product Name: Brand Lovaza, generic omega-3-acid ethyl esters, Brand Vascepa, generic icosapent ethyl |                             |
| Diagnosis                                                                                             | Severe Hypertriglyceridemia |
| Approval Length                                                                                       | 12 month(s)                 |
| Therapy Stage                                                                                         | Initial Authorization       |
| Guideline Type                                                                                        | Prior Authorization         |

### Approval Criteria

**1** - Diagnosis of severe hypertriglyceridemia [pre-treatment triglyceride level of greater than or equal to 500 milligrams/deciliter (mg/dL)]

**AND**

**2** - Patient is on an appropriate lipid-lowering diet and exercise regimen

**AND**

**3** - ONE of the following:

**3.1** Failure to at least 90 days of a fibric acid derivative, as confirmed by claims history or submission of medical records

**OR**

**3.2** History of contraindication or intolerance to a fibric acid derivative (please specify contraindication or intolerance)

**AND**

**4** - If the request is for a non-preferred\* product, ONE of the following:

**4.1** Failure to omega-3-acid ethyl esters (generic Lovaza), as confirmed by claims history or submission of medical records

**OR**

**4.2** History of contraindication or intolerance to omega-3-acid ethyl esters (generic Lovaza) (please specify contraindication or intolerance)

Notes

\*Omega 3-acid esters (generic Lovaza) is preferred. Other omega-3 acid derivatives are non-preferred.

|                                                                                                                                                                                                                                  |                             |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|
| Product Name: Brand Lovaza, generic omega-3-acid ethyl esters, Brand Vascepa, generic icosapent ethyl                                                                                                                            |                             |
| Diagnosis                                                                                                                                                                                                                        | Severe Hypertriglyceridemia |
| Approval Length                                                                                                                                                                                                                  | 12 month(s)                 |
| Therapy Stage                                                                                                                                                                                                                    | Reauthorization             |
| Guideline Type                                                                                                                                                                                                                   | Prior Authorization         |
| <p><b>Approval Criteria</b></p> <p>1 - Documentation of positive clinical response to therapy</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Patient is on an appropriate lipid-lowering diet and exercise regimen</p> |                             |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                               |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|
| Product Name: Brand Vascepa, generic icosapent ethyl                                                                                                                                                                                                                                                                                                                                                                                            |                               |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                       | Cardiovascular Risk Reduction |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                 | 12 month(s)                   |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                   | Initial Authorization         |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                  | Prior Authorization           |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of hypertriglyceridemia [pre-treatment triglyceride level greater than or equal to 150 milligrams/deciliter (mg/dL)]</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Patient currently has or is considered high or very high risk for cardiovascular disease (CVD) as evidenced by ONE of the following:</p> <p>2.1 BOTH of the following:</p> <p>2.1.1 At least 45 years of age</p> |                               |

**AND**

**2.1.2** Established CVD confirmed by ONE of the following:

- Acute coronary syndrome
- History of myocardial infarction
- Stable or unstable angina
- Coronary or other arterial revascularization
- Stroke
- Transient ischemic attack
- Peripheral arterial disease

**OR**

**2.2** ALL of the following:

**2.2.1** Diagnosis of Type 2 diabetes

**AND**

**2.2.2** TWO of the following risk factors for developing cardiovascular disease:

- Men at least 55 years and women at least 65 years
- Cigarette smoker or stopped smoking within the past 3 months
- Hypertension [pretreatment blood pressure greater than or equal to 140 millimeters of mercury (mmHg) systolic or greater than or equal to 90 mmHg diastolic]
- HDL-C (high-density lipoprotein cholesterol) less than or equal to 40 mg/dL for men or less than or equal to 50 mg/dL for women
- High-sensitivity C-reactive protein greater than 3.0 mg/L (liter)
- Creatinine clearance greater than 30 and less than 60 milliliters/minute (mL/min)
- Retinopathy
- Micro- or macro-albuminuria
- Ankle-brachial index (ABI) less than 0.9 without symptoms of intermittent claudication

**AND**

**3** - Submission of medical records (e.g., chart notes, laboratory values) documenting ONE of the following (prescription claims history may be used in conjunction as documentation of medication use, dose, and duration):



**3.1** Patient has been receiving at least 12 consecutive weeks of high-intensity statin therapy (i.e., atorvastatin 40-80 mg, rosuvastatin 20-40 mg) and will continue to receive a high-intensity statin at maximally tolerated dose

**OR**

**3.2** BOTH of the following:

**3.2.1** Patient is unable to tolerate high-intensity statin as evidenced by ONE of the following intolerable and persistent (i.e., more than 2 weeks) symptoms:

- Myalgia [muscle symptoms without creatine kinase (CK) elevations]
- Myositis [muscle symptoms with CK elevations less than 10 times upper limit of normal (ULN)]

**AND**

**3.2.2** Patient has been receiving at least 12 consecutive weeks of low-intensity or moderate-intensity statin therapy [i.e., atorvastatin 10-20 mg, rosuvastatin 5-10 mg, simvastatin greater than or equal to 10 mg, pravastatin greater than or equal to 10 mg, lovastatin 20-40 mg, fluvastatin XL 80 mg, fluvastatin 20-40 mg up to 40 mg twice daily, or Livalo (pitavastatin) greater than or equal to 1 mg] and will continue to receive a low-intensity or moderate-intensity statin at maximally tolerated dose

**AND**

**4** - Submission of medical record (e.g., chart notes, laboratory values) documenting ONE of the following (prescription claims history may be used in conjunction as documentation of medication use, dose, and duration):

**4.1** Patient has been receiving at least 12 consecutive weeks of ezetimibe (generic Zetia) therapy as adjunct to maximally tolerated statin therapy

**OR**

**4.2** History of contraindication or intolerance to ezetimibe (please specify contraindication or intolerance)

**OR**

**4.3** Patient has an LDL-C (low density lipoprotein cholesterol) less than 100 mg/dL while on maximally tolerated statin therapy

**AND**

**5** - Used as an adjunct to a low-fat diet and exercise

**AND**

**6** - Prescribed by or in consultation with ONE of the following:

- Cardiologist
- Endocrinologist
- Lipid specialist

|                                                                                                                                                                                                                                         |                               |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|
| Product Name: Brand Vascepa, generic icosapent ethyl                                                                                                                                                                                    |                               |
| Diagnosis                                                                                                                                                                                                                               | Cardiovascular Risk Reduction |
| Approval Length                                                                                                                                                                                                                         | 12 month(s)                   |
| Therapy Stage                                                                                                                                                                                                                           | Reauthorization               |
| Guideline Type                                                                                                                                                                                                                          | Prior Authorization           |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of positive clinical response to therapy</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Patient is on an appropriate low-fat diet and exercise regimen</p> |                               |

**AND**

**3** - Patient is receiving maximally tolerated statin therapy

## **2 . Revision History**

| Date      | Notes               |
|-----------|---------------------|
| 4/17/2025 | Updated formularies |

Omnipod 5, Twiist



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-243199                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Guideline Name</b> | Omnipod 5, Twiist                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Arizona (ACUAZ, ACUAZEC)</li> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Michigan (ACUMI)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 6/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                                 |                       |
|---------------------------------|-----------------------|
| Product Name: Omnipod 5, Twiist |                       |
| Approval Length                 | 12 month(s)           |
| Therapy Stage                   | Initial Authorization |
| Guideline Type                  | Prior Authorization   |

### **Approval Criteria**

**1 - ONE of the following:**

- For Omnipod 5 product: Diagnosis of diabetes
- For Twist product: Diagnosis of Type 1 diabetes

**AND**

**2 - ALL of the following:**

**2.1** Patient has done ONE of the following for at least 8 weeks:

- Regularly tests blood glucose at least 4 times/day
- Utilizes a continuous glucose monitor (CGM)

**AND**

**2.2** Patient has completed a diabetes management program

**AND**

**2.3** Patient injects insulin at least 3 times/day

**AND**

**3 - BOTH of the following:**

**3.1** Patient or caregiver is motivated to assume responsibility for self-care and insulin management

**AND**

**3.2** Patient or caregiver demonstrates knowledge of importance of nutrition including carbohydrate counting and meal planning

**AND**

**4** - Prescriber attests that there is a reason or special circumstance the patient cannot use external insulin pumps obtained on the medical benefit

|       |                                                            |
|-------|------------------------------------------------------------|
| Notes | If patient meets criteria, approve using NDC List OMNIPOD5 |
|-------|------------------------------------------------------------|

|                                |  |
|--------------------------------|--|
| Product Name:Omnipod 5, Twiist |  |
|--------------------------------|--|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                 |
|---------------|-----------------|
| Therapy Stage | Reauthorization |
|---------------|-----------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

**1** - Documentation of positive clinical response

|       |                                                            |
|-------|------------------------------------------------------------|
| Notes | If patient meets criteria, approve using NDC List OMNIPOD5 |
|-------|------------------------------------------------------------|

|                             |  |
|-----------------------------|--|
| Product Name:Omnipod 5 pods |  |
|-----------------------------|--|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|                |                |
|----------------|----------------|
| Guideline Type | Quantity Limit |
|----------------|----------------|

**Approval Criteria**

**1** - Physician confirmation that the patient requires a greater quantity

|       |                                                                                                                                             |
|-------|---------------------------------------------------------------------------------------------------------------------------------------------|
| Notes | Authorization for quantity limit overrides should be entered at the NDC level for the requested Omnipod 5 pods, for the requested quantity. |
|-------|---------------------------------------------------------------------------------------------------------------------------------------------|

**2 . Revision History**

|      |       |
|------|-------|
| Date | Notes |
|------|-------|

|           |                                                 |
|-----------|-------------------------------------------------|
| 4/22/2025 | Corrected spelling of Twiist in guideline name. |
|-----------|-------------------------------------------------|

OmvoH



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-234204                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Guideline Name</b> | OmvoH                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 6/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                       |                         |
|-----------------------|-------------------------|
| Product Name:OmvoH SC |                         |
| Diagnosis             | Ulcerative Colitis (UC) |
| Approval Length       | 12 month(s)             |
| Therapy Stage         | Initial Authorization   |
| Guideline Type        | Prior Authorization     |



### Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

**AND**

2 - ONE of the following:

- Patient has been established on therapy with Omvoh under an active UnitedHealthcare medical benefit prior authorization for the treatment of moderately to severely active ulcerative colitis
- Patient is currently on Omvoh therapy for subcutaneous use as confirmed by claims history or submission of medical records

**AND**

3 - Patient is NOT receiving Omvoh in combination with another targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Entyvio (vedolizumab), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), ustekinumab, Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), Zeposia (ozanimod)]

**AND**

4 - Prescribed by or in consultation with a gastroenterologist

| Product Name:Omvoh SC |                         |
|-----------------------|-------------------------|
| Diagnosis             | Ulcerative Colitis (UC) |
| Approval Length       | 12 month(s)             |
| Therapy Stage         | Reauthorization         |
| Guideline Type        | Prior Authorization     |
| Approval Criteria     |                         |

**1 - Documentation of positive clinical response to Omvoh therapy**

**AND**

**2 - Patient is NOT receiving Omvoh in combination with another targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Entyvio (vedolizumab), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), ustekinumab, Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), Zeposia (ozanimod)]**

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                       |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Omvoh SC                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                       |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Crohn's Disease (CD)  |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1 - Diagnosis of moderately to severely active Crohn's disease</b></p> <p><b>AND</b></p> <p><b>2 - ONE of the following:</b></p> <ul style="list-style-type: none"> <li>• Patient has been established on therapy with Omvoh under an active UnitedHealthcare medical benefit prior authorization for the treatment of moderately to severely active Crohn's disease</li> <li>• Patient is currently on Omvoh therapy for subcutaneous use for moderately to severely active Crohn's disease as confirmed by claims history or submission of medical records</li> </ul> <p><b>AND</b></p> <p><b>3 - Patient is NOT receiving Omvoh in combination with another targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia</b></p> |                       |

(abatacept), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab-rzaa), ustekinumab, Xeljanz (tofacitinib)]

**AND**

**4** - Prescribed by or in consultation with a gastroenterologist

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                      |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|
| Product Name: Omvoh SC                                                                                                                                                                                                                                                                                                                                                                                                                                          |                      |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Crohn's Disease (CD) |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 12 month(s)          |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Reauthorization      |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Prior Authorization  |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of positive clinical response to Omvoh therapy</p> <p><b>AND</b></p> <p><b>2</b> - Patient is NOT receiving Omvoh in combination with another targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab-rzaa), ustekinumab, Xeljanz (tofacitinib)]</p> |                      |

## 2 . Revision History

| Date     | Notes                 |
|----------|-----------------------|
| 4/8/2025 | Added criteria for CD |

Onureg



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-164740                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Guideline Name</b> | Onureg                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Arizona (ACUAZ, ACUAZEC)</li> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Washington (ACUWA, ACUWAAHE, ACUWAC)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 3/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                      |                        |
|----------------------|------------------------|
| Product Name: Onureg |                        |
| Diagnosis            | Acute Myeloid Leukemia |

|                                                                                                                                                                                                                                                                                                                                                                                                                                              |                       |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                              | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                               | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of acute myeloid leukemia</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Achieved first complete remission (CR) or complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy</p> <p style="text-align: center;"><b>AND</b></p> <p>3 - Patient is not able to complete intensive curative therapy (e.g., transplant-ineligible)</p> |                       |

|                                                                                                                                                                                                                                                                                                                                                                    |                            |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|
| Product Name: Onureg                                                                                                                                                                                                                                                                                                                                               |                            |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                          | Peripheral T-cell Lymphoma |
| Approval Length                                                                                                                                                                                                                                                                                                                                                    | 12 month(s)                |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                      | Initial Authorization      |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                     | Prior Authorization        |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of one of the following T-cell lymphomas:</p> <ul style="list-style-type: none"> <li>• Angioimmunoblastic T-cell lymphoma (AITL)</li> <li>• Nodal peripheral T-cell lymphoma with TFH phenotype (PTCL, TFH)</li> <li>• Follicular T-cell lymphoma (FTCL)</li> </ul> <p style="text-align: center;"><b>AND</b></p> |                            |

**2** - One of the following:

- Used as initial palliative intent therapy
- Used as second-line and subsequent therapy

**Product Name:**Onureg

|           |                                                    |
|-----------|----------------------------------------------------|
| Diagnosis | Acute Myeloid Leukemia, Peripheral T-cell Lymphoma |
|-----------|----------------------------------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                 |
|---------------|-----------------|
| Therapy Stage | Reauthorization |
|---------------|-----------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

**1** - Patient does not show evidence of progressive disease while on Onureg therapy

**Product Name:**Onureg

|           |               |
|-----------|---------------|
| Diagnosis | NCCN Regimens |
|-----------|---------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

**1** - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

**Product Name:**Onureg

|           |               |
|-----------|---------------|
| Diagnosis | NCCN Regimens |
|-----------|---------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                 |
|---------------|-----------------|
| Therapy Stage | Reauthorization |
|---------------|-----------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

1 - There is documentation of positive clinical response to Onureg therapy

**2 . Revision History**

| Date     | Notes                                                              |
|----------|--------------------------------------------------------------------|
| 2/5/2025 | Updated formularies. Added criteria for Peripheral T-cell Lymphoma |

Opfolda



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-228225                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Guideline Name</b> | Opfolda                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania (ACUPA)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 5/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                      |                       |
|----------------------|-----------------------|
| Product Name:Opfolda |                       |
| Approval Length      | 12 month(s)           |
| Therapy Stage        | Initial Authorization |



| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Prior Authorization |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of late-onset Pompe disease as confirmed by ONE of the following:</p> <p><b>1.1</b> Absence or deficiency (less than 40% of the lab specific normal mean) of acid alpha-glucosidase (GAA) activity in lymphocytes, fibroblasts or muscle</p> <p style="text-align: center;"><b>OR</b></p> <p><b>1.2</b> Molecular genetic testing for deletion or mutations in the GAA gene</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Presence of clinical signs and symptoms of the disease (e.g., cardiac hypertrophy, respiratory distress, skeletal muscle weakness, etc.)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Provider attests that the patient is not improving on their current enzyme replacement therapy (ERT) (e.g., Lumizyme, Nexviazyme) for the treatment of late-onset Pompe disease and this therapy will be stopped</p> <p style="text-align: center;"><b>AND</b></p> <p><b>4</b> - Patient weighs at least 40kg</p> <p style="text-align: center;"><b>AND</b></p> <p><b>5</b> - Opfolda will be prescribed in combination with Pombiliti (cipaglucosidase alfa-atga)</p> |                     |
| Product Name:Opfolda                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                     |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 12 month(s)         |

|                                                                                                                                                                                                                                            |                     |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Therapy Stage                                                                                                                                                                                                                              | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                             | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p>1 - Documentation of positive clinical response to Opfolda plus Pombiliti</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Opfolda continues to be prescribed in combination with Pombiliti</p> |                     |

## 2 . Revision History

| Date      | Notes               |
|-----------|---------------------|
| 3/27/2025 | Updated formularies |

Ophthalmic Antihistamine



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-161390                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Guideline Name</b> | Ophthalmic Antihistamine                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 1/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                                    |              |
|------------------------------------|--------------|
| Product Name:azelastine ophth soln |              |
| Approval Length                    | 12 month(s)  |
| Guideline Type                     | Step Therapy |
| Approval Criteria                  |              |

**1** - Failure to Pataday OTC (over-the-counter), as confirmed by claims history or submission of medical records

**OR**

**2** - History of contraindication or intolerance to Pataday OTC (please specify contraindication or intolerance)

Product Name: olopatadine ophth soln (Rx formulation)

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

### Approval Criteria

**1** - ONE of the following:

**1.1** Failure to Pataday OTC (over-the-counter), as confirmed by claims history or submission of medical records

**OR**

**1.2** History of contraindication or intolerance to Pataday OTC (please specify contraindication or intolerance)

**AND**

**2** - ONE of the following:

**2.1** Failure to ONE of the following, as confirmed by claims history or submission of medical records:

- Azelastine ophthalmic solution
- Ketotifen
- Cromolyn

**OR**

**2.2** History of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):

- Azelastine ophthalmic solution
- Ketotifen
- Cromolyn

## 2 . Revision History

| Date       | Notes                                                                                                             |
|------------|-------------------------------------------------------------------------------------------------------------------|
| 11/27/2024 | Removed CO (RMHCAID, RMHCHP, RMHWRP) formulary from benefit coverage section. No other changes to guideline made. |

Opzelura



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                   |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-395196                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Guideline Name</b> | Opzelura                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 10/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                       |                       |
|-----------------------|-----------------------|
| Product Name:Opzelura |                       |
| Diagnosis             | Atopic Dermatitis     |
| Approval Length       | 12 month(s)           |
| Therapy Stage         | Initial Authorization |
| Guideline Type        | Prior Authorization   |
| Approval Criteria     |                       |

**1 - Diagnosis of mild to moderate atopic dermatitis**

**AND**

**2 - ONE of the following:**

**2.1** Patient is currently on Opzelura therapy as confirmed by claims history or submission of medical records

**OR**

**2.2** For mild atopic dermatitis:

**2.2.1** Failure to TWO of the following topical therapeutic classes as confirmed by claims history or submission of medical records:

- A topical corticosteroid [e.g., DesOwen (desonide), hydrocortisone] (any potency)
- One topical calcineurin inhibitor [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)]
- Eucrisa (crisaborole)

**OR**

**2.2.2** History of intolerance or contraindication to ALL of the following topical therapeutic classes (please specify intolerance or contraindication):

- A topical corticosteroid [e.g., DesOwen (desonide), hydrocortisone] (any potency)
- One topical calcineurin inhibitor [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)]
- Eucrisa (crisaborole)

**OR**

**2.3** For moderate atopic dermatitis:

**2.3.1** Failure to TWO of the following topical therapeutic classes as confirmed by claims history or submission of medical records:

- A topical corticosteroid of at least a medium- to high-potency topical corticosteroid [e.g., Elocon (mometasone furoate), Synalar (fluocinolone acetonide), Lidex (fluocinonide)]
- One topical calcineurin inhibitor [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)]

- Eucrisa (crisaborole)

**OR**

**2.3.2** History of intolerance or contraindication to ALL of the following topical therapeutic classes (please specify intolerance or contraindication):

- A topical corticosteroid of at least a medium- to high-potency topical corticosteroid [e.g., Elocon (mometasone furoate), Synalar (fluocinolone acetonide), Lidex (fluocinonide)]
- One topical calcineurin inhibitor [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)]
- Eucrisa (crisaborole)

**AND**

**3** - Patient is NOT receiving Opzelura in combination with another biologic medication [e.g., Dupixent (dupilumab), Xolair (omalizumab), Rituxan (rituximab), Enbrel (etanercept), Avsola/Inflectra (infliximab)] nor JAK inhibitor [e.g., Jakafi (ruxolitinib), Xeljanz (tofacitinib), Rinvoq (upadacitinib)]

**AND**

**4** - Patient is NOT receiving Opzelura in combination with a potent immunosuppressant medication (e.g., azathioprine, cyclosporine)

|                                                                                      |                       |
|--------------------------------------------------------------------------------------|-----------------------|
| Product Name:Opzelura                                                                |                       |
| Diagnosis                                                                            | Nonsegmental Vitiligo |
| Approval Length                                                                      | 12 month(s)           |
| Therapy Stage                                                                        | Initial Authorization |
| Guideline Type                                                                       | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of nonsegmental vitiligo</p> |                       |



**AND**

**2** - Other causes of depigmentation have been ruled out [e.g., nevus depigmentosus, pityriasis alba, idiopathic guttate hypomelanosis, tinea (pityriasis) versicolor, halo nevus, piebaldism, progressive macular hypomelanosis, lichen sclerosus, chemical leukoderma, drug-induced leukoderma, hypopigmented mycosis fungoides]

**AND**

**3** - Affected areas do not exceed 10% body surface area

**AND**

**4** - ONE of the following:

**4.1** Failure to a previous nonsegmental vitiligo treatment(s) (e.g., topical corticosteroids, topical calcineurin inhibitors) as confirmed by claims history or submission of medical records

**OR**

**4.2** History of intolerance or contraindication to one previous nonsegmental vitiligo treatment(s) (e.g., topical corticosteroids, topical calcineurin inhibitors) (please specify intolerance or contraindication)

**AND**

**5** - Patient is NOT receiving Opzelura in combination with another biologic medication [e.g., Dupixent (dupilumab), Xolair (omalizumab), Rituxan (rituximab), Enbrel (etanercept), Avsola/Inflectra (infliximab)] or JAK inhibitor [e.g., Jakafi (ruxolitinib), Xeljanz (tofacitinib), Rinvoq (upadacitinib)]

**AND**

**6** - Patient is NOT receiving Opzelura in combination with a potent immunosuppressant medication (e.g., azathioprine, cyclosporine)

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                          |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------|
| Product Name:Opzelura                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                          |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Atopic Dermatitis, Nonsegmental Vitiligo |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 12 month(s)                              |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Reauthorization                          |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Prior Authorization                      |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of positive clinical response to therapy</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Patient is NOT receiving Opzelura in combination with another biologic medication [e.g., Dupixent (dupilumab), Xolair (omalizumab), Rituxan (rituximab), Enbrel (etanercept), Avsola/Inflectra (infliximab)] nor JAK inhibitor [e.g., Jakafi (ruxolitinib), Xeljanz (tofacitinib), Rinvoq (upadacitinib)]</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Patient is NOT receiving Opzelura in combination with a potent immunosuppressant medication (e.g., azathioprine, cyclosporine)</p> |                                          |

## 2 . Revision History

| Date      | Notes                            |
|-----------|----------------------------------|
| 9/10/2025 | Removed WA from core GL version. |

Orencia



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-206565                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Guideline Name</b> | Orencia                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 4/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                      |                           |
|----------------------|---------------------------|
| Product Name:Orencia |                           |
| Diagnosis            | Rheumatoid Arthritis (RA) |
| Approval Length      | 12 month(s)               |
| Therapy Stage        | Initial Authorization     |
| Guideline Type       | Prior Authorization       |

## **Approval Criteria**

**1** - ALL of the following:

**1.1** Diagnosis of moderately to severely active rheumatoid arthritis

**AND**

**1.2** One of the following:

**1.2.1** Failure to a 3 month trial of one non-biologic disease modifying anti-rheumatic drug (DMARD) [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine] at maximally indicated doses as confirmed by claims history or submitted medical records

**OR**

**1.2.2** History of intolerance or contraindication to one non-biologic disease modifying anti-rheumatic drug (DMARD) [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine] (please specify intolerance or contraindication)

**OR**

**1.2.3** Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of rheumatoid arthritis as confirmed by claims history or submission of medical records [e.g., Cimzia (certolizumab), adalimumab, Simponi (golimumab), Olumiant (baricitinib), Rinvoq (upadacitinib), Xeljanz/Xeljanz XR (tofacitinib)]

**AND**

**1.3** Patient is NOT receiving Orencia in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

**AND**

**1.4** ONE of the following:

**1.4.1 BOTH of the following:**

**1.4.1.1** Failure of one of the preferred adalimumab products\*, confirmed by claims history or submitted medical records

**AND**

**1.4.1.2** Failure of TWO of the following confirmed by claims history or submitted medical records:

- Enbrel (etanercept)
- Olumiant (baricitinib)
- Tyenne (tocilizumab-aazg)

**OR**

**1.4.2** History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication):

- One of the preferred adalimumab products\*
- Enbrel (etanercept)
- Olumiant (baricitinib)
- Tyenne (tocilizumab-aazg)

**AND**

**1.5** Prescribed by, or in consultation with, a rheumatologist

**OR**

**2 - ALL of the following:**

**2.1** Patient is currently on Orencia therapy as confirmed by claims history or submitted medical records

**AND**

**2.2** Diagnosis of moderately to severely active rheumatoid arthritis

**AND**

**2.3** Patient is NOT receiving Orenzia in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

**AND**

**2.4** Prescribed by, or in consultation with, a rheumatologist

|       |                              |
|-------|------------------------------|
| Notes | *See PDL links in Background |
|-------|------------------------------|

|                                                                                                                                                                                                                                                                                                                                                                          |                       |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Orenzia                                                                                                                                                                                                                                                                                                                                                     |                       |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                | Psoriatic Arthritis   |
| Approval Length                                                                                                                                                                                                                                                                                                                                                          | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                            | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                           | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - ALL of the following:</p> <p><b>1.1</b> Diagnosis of active psoriatic arthritis</p> <p><b>AND</b></p> <p><b>1.2</b> ONE of the following:</p> <p><b>1.2.1</b> Failure to a 3 month trial of methotrexate at the maximally indicated dose confirmed by claims history or submission of medical records</p> <p><b>OR</b></p> |                       |

**1.2.2** History of intolerance or contraindication to methotrexate (please specify intolerance or contraindication)

**OR**

**1.2.3** Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of psoriatic arthritis as confirmed by claims history or submission of medical records [e.g., Cimzia (certolizumab), adalimumab, Simponi (golimumab), ustekinumab, Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), Otezla (apremilast), Skyrizi (risankizumab-rzaa)]

**AND**

**1.3** Patient is NOT receiving Orencia in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

**AND**

**1.4** BOTH of the following:

**1.4.1** ONE of the following:

**1.4.1.1** Failure to TWO of the following as confirmed by claims history or submission of medical records:

- One of the preferred adalimumab products\*
- Enbrel (etanercept)
- One of the preferred ustekinumab products\*

**OR**

**1.4.1.2** History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication):

- One of the preferred adalimumab products\*
- Enbrel (etanercept)

- One of the preferred ustekinumab products\*

**AND**

**1.4.2** ONE of the following:

**1.4.2.1** Failure to Cosentyx (secukinumab) as confirmed by claims history or submission of medical records

**OR**

**1.4.2.2** History of intolerance or contraindication to Cosentyx (secukinumab) (please specify intolerance or contraindication)

**AND**

**1.5** Prescribed by, or in consultation with, ONE of the following:

- Rheumatologist
- Dermatologist

**OR**

**2** - ALL of the following:

**2.1** Patient is currently on Orencia therapy as confirmed by claims history or submitted medical records

**AND**

**2.2** Diagnosis of active psoriatic arthritis

**AND**

**2.3** Patient is NOT receiving Orencia in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz



(ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

**AND**

**2.4** Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Dermatologist

Notes

\*See PDL links in Background

Product Name: Orenzia

|           |                                                    |
|-----------|----------------------------------------------------|
| Diagnosis | Polyarticular Juvenile Idiopathic Arthritis (PJIA) |
|-----------|----------------------------------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

### Approval Criteria

**1** - Diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis

**AND**

**2** - Patient is NOT receiving Orenzia in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

**AND**

**3** - ONE of the following:

**3.1** Failure to ALL of the following as confirmed by claims history or submission of medical records:

- One of the preferred adalimumab products\*

- Enbrel (etanercept)
- Tyenne (tocilizumab-aazg)

**OR**

**3.2** History of contraindication or intolerance to ALL of the following (please specify intolerance or contraindication):

- One of the preferred adalimumab products\*
- Enbrel (etanercept)
- Tyenne (tocilizumab-aazg)

**OR**

**3.3** Patient is currently on Orenzia therapy as confirmed by claims history or submitted medical records

**AND**

**4** - Prescribed by, or in consultation with, a rheumatologist

|       |                              |
|-------|------------------------------|
| Notes | *See PDL links in Background |
|-------|------------------------------|

|                                                                                                                                    |                                                                                                    |
|------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|
| Product Name:Orenzia                                                                                                               |                                                                                                    |
| Diagnosis                                                                                                                          | Rheumatoid Arthritis (RA), Psoriatic Arthritis, Polyarticular Juvenile Idiopathic Arthritis (PJIA) |
| Approval Length                                                                                                                    | 12 month(s)                                                                                        |
| Therapy Stage                                                                                                                      | Reauthorization                                                                                    |
| Guideline Type                                                                                                                     | Prior Authorization                                                                                |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of positive clinical response to Orenzia therapy</p> <p><b>AND</b></p> |                                                                                                    |

**2** - Patient is NOT receiving Ocrencia in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]\*

Notes

\*Examples of drug(s) may not be applicable based on the requested indication.

## 2 . Background

### Benefit/Coverage/Program Information

#### PDL Links

CO: <https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html>

HI: <https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html>

MD: <https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-cp-pharmacy.html>

NJ: <https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html>

NY: <https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html>

PA: <https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP>

RI: <https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html>

NM: <https://www.uhcprovider.com/en/health-plans-by-state/new-mexico-health-plans/nm-comm-plan-home/nm-cp-pharmacy.html>

### 3 . Revision History

| Date     | Notes                                                                                   |
|----------|-----------------------------------------------------------------------------------------|
| 3/4/2025 | Added ustekinumab as a step therapy option in PsA. Changed "Stelara" to "ustekinumab" . |

Orgovyx



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-219253                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Guideline Name</b> | Orgovyx                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Arizona (ACUAZ, ACUAZEC)</li> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Washington (ACUWA, ACUWAAHE, ACUWAC)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 5/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                       |                 |
|-----------------------|-----------------|
| Product Name: Orgovyx |                 |
| Diagnosis             | Prostate Cancer |
| Approval Length       | 12 month(s)     |

|                                                                              |                       |
|------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                | Initial Authorization |
| Guideline Type                                                               | Prior Authorization   |
| <b>Approval Criteria</b><br><b>1 - Diagnosis of advanced prostate cancer</b> |                       |

|                                                                                                                       |                     |
|-----------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Orgovyx                                                                                                  |                     |
| Diagnosis                                                                                                             | Prostate Cancer     |
| Approval Length                                                                                                       | 12 month(s)         |
| Therapy Stage                                                                                                         | Reauthorization     |
| Guideline Type                                                                                                        | Prior Authorization |
| <b>Approval Criteria</b><br><b>1 - Patient does not show evidence of progressive disease while on Orgovyx therapy</b> |                     |

|                                                                                                                                            |                           |
|--------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Orgovyx                                                                                                                       |                           |
| Diagnosis                                                                                                                                  | NCCN Recommended Regimens |
| Approval Length                                                                                                                            | 12 month(s)               |
| Therapy Stage                                                                                                                              | Initial Authorization     |
| Guideline Type                                                                                                                             | Prior Authorization       |
| <b>Approval Criteria</b><br><b>1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium</b> |                           |

|                      |                           |
|----------------------|---------------------------|
| Product Name:Orgovyx |                           |
| Diagnosis            | NCCN Recommended Regimens |
| Approval Length      | 12 month(s)               |

|                                                                                                    |                     |
|----------------------------------------------------------------------------------------------------|---------------------|
| Therapy Stage                                                                                      | Reauthorization     |
| Guideline Type                                                                                     | Prior Authorization |
| <b>Approval Criteria</b><br><br>1 - Documentation of positive clinical response to Orgovyx therapy |                     |

## 2 . Revision History

| Date      | Notes                                                                                                                                   |
|-----------|-----------------------------------------------------------------------------------------------------------------------------------------|
| 3/14/2025 | Combined formularies. Updated initial auth criteria section for prostate cancer and minor update in reauth section for prostate cancer. |

Oriahnn\_MyFembree



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-224251                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Guideline Name</b> | Oriahnn_MyFembree                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 5/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                                 |                       |
|---------------------------------|-----------------------|
| Product Name:Oriahnn, MyFembree |                       |
| Diagnosis                       | Uterine Fibroids      |
| Approval Length                 | 12 month(s)           |
| Therapy Stage                   | Initial Authorization |
| Guideline Type                  | Prior Authorization   |



## **Approval Criteria**

**1** - Diagnosis of uterine fibroids (leiomyomas)

**AND**

**2** - Used for the management of heavy menstrual bleeding

**AND**

**3** - ONE of the following:

**3.1** Failure after a three-month trial to ONE of the following as confirmed by claims history or submission of medical records:

- Estrogen/progestin contraceptive (e.g., Loestrin FE)
- Progestin-releasing intrauterine devices (IUDs) (e.g., Mirena)\*
- Progestin-only contraceptive [e.g., norethindrone (generic Aygestin)]

**OR**

**3.2** Contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):

- Estrogen/progestin contraceptive (e.g., Loestrin FE)
- Progestin-releasing intrauterine devices (IUDs) (e.g., Mirena)\*
- Progestin-only contraceptive [e.g., norethindrone (generic Aygestin)]

**AND**

**4** - ONE of the following:

- Failure after a three-month trial of tranexamic acid (e.g., Lysteda) as confirmed by claims history or submission of medical records
- History of contraindication or intolerance to tranexamic acid (e.g., Lysteda) (please specify contraindication or intolerance)

|                                                                                                                                                                                                     |                            |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|
| <b>AND</b>                                                                                                                                                                                          |                            |
| <b>5</b> - Prescribed by or in consultation with ONE of the following: <ul style="list-style-type: none"> <li>• Obstetrics/Gynecologist (OB/GYN)</li> <li>• Reproductive endocrinologist</li> </ul> |                            |
| Notes                                                                                                                                                                                               | *This is a medical benefit |

|                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                 |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Product Name:OriaHnn, MyFembree                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                 |
| Diagnosis                                                                                                                                                                                                                                                                                                                                              | Uterine Fibroids                                                                                                                                                                |
| Approval Length                                                                                                                                                                                                                                                                                                                                        | 12 months*                                                                                                                                                                      |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                          | Reauthorization                                                                                                                                                                 |
| Guideline Type                                                                                                                                                                                                                                                                                                                                         | Prior Authorization                                                                                                                                                             |
| <b>Approval Criteria</b><br><br><b>1</b> - Documentation of positive clinical response to therapy<br><br><div style="text-align: center;"><b>AND</b></div> <b>2</b> - Impact to bone mineral density has been considered<br><br><div style="text-align: center;"><b>AND</b></div> <b>3</b> - Treatment duration has not exceeded a total of 24 months* |                                                                                                                                                                                 |
| Notes                                                                                                                                                                                                                                                                                                                                                  | *Authorization will be issued for 12 months up to a maximum treatment duration of 24 months. OriaHnn and MyFembree are indicated for a maximum treatment duration of 24 months. |

|                        |                                    |
|------------------------|------------------------------------|
| Product Name:MyFembree |                                    |
| Diagnosis              | Pain Associated with Endometriosis |
| Approval Length        | 12 month(s)                        |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                       |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of moderate to severe pain associated with endometriosis</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - ONE of the following:</p> <ul style="list-style-type: none"> <li>• Failure (e.g., inadequate pain relief) to a three-month trial of TWO analgesics (e.g., ibuprofen, meloxicam, naproxen) as confirmed by claims history or submission of medical records</li> <li>• History of contraindication or intolerance to TWO analgesics (e.g., ibuprofen, meloxicam, naproxen) (please specify contraindication or intolerance)</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - ONE of the following:</p> <p><b>3.1</b> Failure to a three-month trial of ONE of the following, as confirmed by claims history or submission of medical records:</p> <ul style="list-style-type: none"> <li>• Hormonal contraceptives</li> <li>• Progestins [e.g., norethindrone (generic Aygestin)]</li> </ul> <p style="text-align: center;"><b>OR</b></p> <p><b>3.2</b> History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):</p> <ul style="list-style-type: none"> <li>• Hormonal contraceptives</li> <li>• Progestins [e.g., norethindrone (generic Aygestin)]</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>4</b> - Prescribed by or in consultation with ONE of the following:</p> |                       |

- Obstetrics/Gynecologist (OB/GYN)
- Reproductive endocrinologist

|                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                     |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Product Name: MyFembree                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                     |
| Diagnosis                                                                                                                                                                                                                                                                                                                        | Pain Associated with Endometriosis                                                                                                                                  |
| Approval Length                                                                                                                                                                                                                                                                                                                  | 12 months*                                                                                                                                                          |
| Therapy Stage                                                                                                                                                                                                                                                                                                                    | Reauthorization                                                                                                                                                     |
| Guideline Type                                                                                                                                                                                                                                                                                                                   | Prior Authorization                                                                                                                                                 |
| <p><b>Approval Criteria</b></p> <p>1 - Documentation of positive clinical response to therapy</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Impact to bone mineral density has been considered</p> <p style="text-align: center;"><b>AND</b></p> <p>3 - Treatment duration has not exceeded a total of 24 months*</p> |                                                                                                                                                                     |
| Notes                                                                                                                                                                                                                                                                                                                            | *Authorization will be issued for 12 months up to a maximum treatment duration of 24 months. MyFembree are indicated for a maximum treatment duration of 24 months. |

## 2 . Revision History

| Date      | Notes                                                                       |
|-----------|-----------------------------------------------------------------------------|
| 3/25/2025 | Updated formularies. Updated medical benefit note. Minor formatting changes |

Orilissa



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-224255                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Guideline Name</b> | Orilissa                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 5/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                              |                       |
|------------------------------|-----------------------|
| Product Name:Orilissa 150 mg |                       |
| Approval Length              | 12 month(s)           |
| Therapy Stage                | Initial Authorization |
| Guideline Type               | Prior Authorization   |

### **Approval Criteria**

**1** - Diagnosis of moderate to severe pain associated with endometriosis

**AND**

**2** - ONE of the following:

**2.1** Failure (e.g., inadequate pain relief) to a three month trial of TWO analgesics (e.g., ibuprofen, meloxicam, naproxen) as confirmed by claims history or submission of medical records

**OR**

**2.2** History of contraindication or intolerance to TWO analgesics (e.g., ibuprofen, meloxicam, naproxen) (please specify contraindication or intolerance)

**AND**

**3** - ONE of the following:

**3.1** Failure to a three month trial to ONE of the following as confirmed by claims history or submission of medical records:

- Hormonal contraceptives
- Progestins [e.g., norethindrone (generic Aygestin)]

**OR**

**3.2** History of contraindication or intolerance to BOTH of the following (please specify contraindication or intolerance)

- Hormonal contraceptives
- Progestins [e.g., norethindrone (generic Aygestin)]

**AND**

**4** - Treatment duration of Orilissa 150 mg once daily has not exceeded a total of 24 months, as confirmed by claims history or submission of medical records

**AND**

**5** - Prescribed by or in consultation with ONE of the following:

- Obstetrics/Gynecologist (OB/GYN)
- Reproductive endocrinologist

|                                                                                                                                                                                                                                                                                                                                                               |                                                           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------|
| Product Name:Orilissa 150 mg                                                                                                                                                                                                                                                                                                                                  |                                                           |
| Approval Length                                                                                                                                                                                                                                                                                                                                               | 12 months up to a maximum treatment duration of 24 months |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                 | Reauthorization                                           |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                | Prior Authorization                                       |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of positive clinical response to therapy</p> <p><b>AND</b></p> <p><b>2</b> - Impact to bone mineral density has been considered</p> <p><b>AND</b></p> <p><b>3</b> - Treatment duration has not exceeded a total of 24 months, as confirmed by claims history or submission of medical records</p> |                                                           |

|                              |                             |
|------------------------------|-----------------------------|
| Product Name:Orilissa 200 mg |                             |
| Approval Length              | Up to a maximum of 6 months |
| Guideline Type               | Prior Authorization         |

**Approval Criteria**

**1** - Diagnosis of moderate to severe pain associated with endometriosis

**AND**

**2** - ONE of the following:

**2.1** Failure (e.g., inadequate pain relief) to a three month trial of TWO analgesics (e.g., ibuprofen, meloxicam, naproxen), as confirmed by claims history or submission of medical records

**OR**

**2.2** History of intolerance or contraindication to TWO analgesics (e.g., ibuprofen, meloxicam, naproxen) (please specify intolerance or contraindication)

**AND**

**3** - ONE of the following:

**3.1** Failure after a three month trial to ONE of the following as confirmed by claims history or submission of medical records:

- Hormonal contraceptives
- Progestins [e.g., norethindrone (generic Aygestin)]

**OR**

**3.2** History of contraindication or intolerance to BOTH of the following (please specify contraindication or intolerance):

- Hormonal contraceptives
- Progestins [e.g., norethindrone (generic Aygestin)]

**AND**



**4** - Treatment duration of Orilissa 200 mg twice daily has not exceeded a total of 6 months, as confirmed by claims history or submission of medical records

**AND**

**5** - Prescribed by or in consultation with ONE of the following:

- Obstetrics/Gynecologist (OB/GYN)
- Reproductive endocrinologist

## 2 . Revision History

| Date      | Notes               |
|-----------|---------------------|
| 3/25/2025 | Updated formularies |

Orkambi



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-151768                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Guideline Name</b> | Orkambi                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 9/1/2024 |
|-----------------|----------|

## 1 . Criteria

|                      |                       |
|----------------------|-----------------------|
| Product Name:Orkambi |                       |
| Approval Length      | 12 month(s)           |
| Therapy Stage        | Initial Authorization |
| Guideline Type       | Prior Authorization   |
|                      |                       |

**Approval Criteria**

**1** - Diagnosis of cystic fibrosis (CF)

**AND**

**2** - Submission of laboratory results confirming that patient is homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene

**AND**

**3** - The patient is greater than or equal to 1 years of age

**AND**

**4** - Prescribed by, or in consultation with, a provider who specializes in the treatment of CF

|                                                                                                                                                                       |                     |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Orkambi                                                                                                                                                  |                     |
| Approval Length                                                                                                                                                       | 12 month(s)         |
| Therapy Stage                                                                                                                                                         | Reauthorization     |
| Guideline Type                                                                                                                                                        | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of positive clinical response to Orkambi therapy (e.g., improved lung function, stable lung function)</p> |                     |

## 2 . Revision History

| Date      | Notes                                                        |
|-----------|--------------------------------------------------------------|
| 8/14/2024 | Removed prescriber requirement from reauthorization criteria |

Orladeyo



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-242228                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Guideline Name</b> | Orladeyo                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 6/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                       |                       |
|-----------------------|-----------------------|
| Product Name:Orladeyo |                       |
| Approval Length       | 12 month(s)           |
| Therapy Stage         | Initial Authorization |
| Guideline Type        | Prior Authorization   |

## **Approval Criteria**

**1** - Diagnosis of hereditary angioedema (HAE) as confirmed by ONE of the following:

**1.1** C1 inhibitor (C1-INH) deficiency or dysfunction (Type I or II HAE) as documented by ONE of the following (per laboratory standard):

- C1-INH antigenic level below the lower limit of normal
- C1-INH functional level below the lower limit of normal

**OR**

**1.2** HAE with normal C1 inhibitor levels and ONE of the following:

- Confirmed presence of variant(s) in the gene(s) for factor XII, angiopoietin-1, plasminogen-1, kininogen-1, myoferlin, and heparan sulfate-glucosamine 3-O-sulfotransferase 6
- Recurring angioedema attacks that are refractory to high-dose antihistamines with confirmed family history of angioedema
- Recurring angioedema attacks that are refractory to high-dose antihistamines with unknown background de-novo mutation(s) (i.e., no family history) (HAE-unknown)

**AND**

**2** - ALL of the following:

**2.1** Prescribed for the prophylaxis of HAE attacks

**AND**

**2.2** Not used in combination with other approved products indicated for prophylaxis against HAE attacks (i.e., Cinryze, Haegarda, Takhzyro)

**AND**

**2.3** Prescriber attests that patient has experienced attacks of a severity and/or frequency such that they would clinically benefit from prophylactic therapy with Orladeyo

**AND**

**3** - Prescribed by ONE of the following:

- Immunologist
- Allergist

**AND**

**4** - ONE of the following:

**4.1** Failure to Haegarda as confirmed by history or submission of medical records

**OR**

**4.2** History of contraindication, or intolerance to Haegarda (please specify a contraindication or intolerance)

**OR**

**4.3** Patient is unable to self-inject Haegarda due to ONE of the following:

- Physical impairment
- Visual impairment
- Lipohypertrophy
- Documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure [refer to DSM-5 (Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition) for specific phobia diagnostic criteria]

**OR**

**4.4** Patient is currently on Orladeyo therapy, as confirmed by claims history or submission of medical records

|                       |             |
|-----------------------|-------------|
| Product Name:Orladeyo |             |
| Approval Length       | 12 month(s) |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                     |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of positive clinical response to Orladeyo therapy</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Reduction in the utilization of on-demand therapies used for acute attacks (e.g., Berinert, Firazyr, Ruconest), as confirmed by claims history or submission of medical records, while on Orladeyo therapy</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - BOTH of the following:</p> <p><b>3.1</b> Prescribed for the prophylaxis of HAE attacks</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3.2</b> Not used in combination with other products indicated for prophylaxis against HAE attacks (i.e., Cinryze, Haegarda, Takhzyro)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>4</b> - Prescribed by ONE of the following:</p> <ul style="list-style-type: none"> <li>• Immunologist</li> <li>• Allergist</li> </ul> |                     |

## 2 . Revision History

UnitedHealthcare Community Plan of New Jersey – Clinical Pharmacy Guidelines

| Date      | Notes               |
|-----------|---------------------|
| 4/17/2025 | Updated formularies |



Orserdu



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-239261                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Guideline Name</b> | Orserdu                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Washington (ACUWA, ACUWAAHE, ACUWAC)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 6/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                      |               |
|----------------------|---------------|
| Product Name:Orserdu |               |
| Diagnosis            | Breast Cancer |
| Approval Length      | 12 month(s)   |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                       |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of breast cancer</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - ONE of the following:</p> <ul style="list-style-type: none"> <li>• Advanced</li> <li>• Metastatic</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Disease is estrogen receptor (ER)-positive</p> <p style="text-align: center;"><b>AND</b></p> <p><b>4</b> - Disease is human epidermal growth factor receptor 2 (HER2)-negative</p> <p style="text-align: center;"><b>AND</b></p> <p><b>5</b> - Presence of an ESR1 gene mutation</p> <p style="text-align: center;"><b>AND</b></p> <p><b>6</b> - Patient is ONE of the following:</p> <ul style="list-style-type: none"> <li>• Postmenopausal woman</li> <li>• Male</li> <li>• Premenopausal woman treated with ovarian ablation/suppression</li> </ul> |                       |

**AND**

**7** - Disease has progressed following at least one line of endocrine therapy

Product Name: Orserdu

|           |               |
|-----------|---------------|
| Diagnosis | Breast Cancer |
|-----------|---------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                 |
|---------------|-----------------|
| Therapy Stage | Reauthorization |
|---------------|-----------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

**1** - Patient does not show evidence of progressive disease while on Orserdu therapy

Product Name: Orserdu

|           |                           |
|-----------|---------------------------|
| Diagnosis | NCCN Recommended Regimens |
|-----------|---------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

**1** - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Orserdu

|           |                           |
|-----------|---------------------------|
| Diagnosis | NCCN Recommended Regimens |
|-----------|---------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                 |
|---------------|-----------------|
| Therapy Stage | Reauthorization |
|---------------|-----------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

1 - Documentation of positive clinical response to Orserdu therapy

**2 . Revision History**

| Date      | Notes                                                  |
|-----------|--------------------------------------------------------|
| 4/16/2025 | Combined formularies. No changes to clinical criteria. |

Osphena



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-242229                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Guideline Name</b> | Osphena                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State Michigan (ACUMI)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania (ACUPA)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 6/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                       |                       |
|-----------------------|-----------------------|
| Product Name: Osphena |                       |
| Approval Length       | 12 month(s)           |
| Therapy Stage         | Initial Authorization |

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Prior Authorization                               |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------|
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy (VVA), due to menopause*</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - ONE of the following:</p> <p><b>2.1</b> Failure to BOTH of the following as confirmed by claims history or submission of medical records:</p> <ul style="list-style-type: none"> <li>• Estradiol vaginal cream</li> <li>• Estradiol vaginal tablet</li> </ul> <p style="text-align: center;"><b>OR</b></p> <p><b>2.2</b> History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):</p> <ul style="list-style-type: none"> <li>• Estradiol vaginal cream</li> <li>• Estradiol vaginal tablet</li> </ul> |                                                   |
| Notes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | *Treatment of dyspareunia is a benefit exclusion. |

|                                                                                                          |                     |
|----------------------------------------------------------------------------------------------------------|---------------------|
| Product Name: Osphena                                                                                    |                     |
| Approval Length                                                                                          | 12 month(s)         |
| Therapy Stage                                                                                            | Reauthorization     |
| Guideline Type                                                                                           | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of positive clinical response to therapy</p> |                     |

## 2 . Revision History

| Date      | Notes               |
|-----------|---------------------|
| 4/17/2025 | Updated formularies |

Otezla



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-205230                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Guideline Name</b> | Otezla                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 4/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                     |                       |
|---------------------|-----------------------|
| Product Name:Otezla |                       |
| Diagnosis           | Psoriatic Arthritis   |
| Approval Length     | 12 month(s)           |
| Therapy Stage       | Initial Authorization |
| Guideline Type      | Prior Authorization   |



**Approval Criteria**

**1** - All of the following:

**1.1** Diagnosis of active psoriatic arthritis

**AND**

**1.2** One of the following:

**1.2.1** Failure to a 3 month trial of methotrexate at the maximally indicated dose, as confirmed by claims history or submission of medical records

**OR**

**1.2.2** History of intolerance or contraindication to methotrexate (please specify intolerance or contraindication)

**OR**

**1.2.3** Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of psoriatic arthritis as confirmed by claims history or submission of medical records [e.g., Cimzia (certolizumab), Simponi (golimumab), ustekinumab, Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), Skyrizi (risankizumab-rzaa)]

**AND**

**1.3** Patient is not receiving Otezla in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

**AND**

**1.4** Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Dermatologist

**OR**

**2** - All of the following:

**2.1** Patient is currently on Otezla therapy as confirmed by claims history or submission of medical records

**AND**

**2.2** Diagnosis of active psoriatic arthritis

**AND**

**2.3** Patient is not receiving Otezla in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

**AND**

**2.4** Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Dermatologist

|                     |                       |
|---------------------|-----------------------|
| Product Name:Otezla |                       |
| Diagnosis           | Plaque Psoriasis      |
| Approval Length     | 12 month(s)           |
| Therapy Stage       | Initial Authorization |
| Guideline Type      | Prior Authorization   |

## **Approval Criteria**

**1** - All of the following:

**1.1** Diagnosis of plaque psoriasis in those who are candidates for phototherapy or systemic therapy

**AND**

**1.2** One of the following:

**1.2.1** All of the following:

**1.2.1.1** Greater than or equal to 3 percent body surface area involvement, palmoplantar, facial, or genital involvement, or severe scalp psoriasis

**AND**

**1.2.1.2** One of the following:

**1.2.1.2.1** Failure to ONE of the following topical therapy classes confirmed by claims history or submission of medical records:

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin
- Coal tar

**OR**

**1.2.1.2.2** History of intolerance or contraindication to ALL of the following topical therapy classes (please specify intolerance or contraindication)

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin

- Coal tar

**AND**

**1.2.1.3** One of the following:

**1.2.1.3.1** Failure to a 3 month trial of methotrexate at the maximally indicated dose confirmed by claims history or submission of medical records

**OR**

**1.2.1.3.2** History of intolerance or contraindication to methotrexate (please specify intolerance or contraindication)

**OR**

**1.2.2** Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of plaque psoriasis as confirmed by claims history or submission of medical records [e.g., Cimzia (certolizumab), Skyrizi (risankizumab-rzaa), ustekinumab, Tremfya (guselkumab)]

**AND**

**1.3** Patient is not receiving Otezla in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

**AND**

**1.4** Prescribed by or in consultation with a dermatologist

**OR**

**2** - All of the following:

**2.1** Patient is currently on Otezla therapy as confirmed by claims history or submission of medical records

**AND**

**2.2** Diagnosis of plaque psoriasis in those who are candidates for phototherapy or systemic therapy

**AND**

**2.3** Patient is not receiving Otezla in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

**AND**

**2.4** Prescribed by or in consultation with a dermatologist

|                                                                                                                                           |                       |
|-------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Otezla                                                                                                                       |                       |
| Diagnosis                                                                                                                                 | Behcet's Disease      |
| Approval Length                                                                                                                           | 12 month(s)           |
| Therapy Stage                                                                                                                             | Initial Authorization |
| Guideline Type                                                                                                                            | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - All of the following:</p> <p><b>1.1</b> Diagnosis of Behcet's Disease</p> <p><b>AND</b></p> |                       |

**1.2 Patient has active oral ulcers attributed to Behcet's Disease**

**AND**

**1.3 One of the following:**

**1.3.1 Failure to one non-biologic (e.g., corticosteroids, colchicine) used for treating Behcet's Disease, as confirmed by claims history or submission of medical records**

**OR**

**1.3.2 History of contraindication or intolerance to one non-biologic (e.g., corticosteroids, colchicine) used for treating Behcet's Disease (please specify contraindication or intolerance)**

**OR**

**1.3.3 Patient has been previously treated with a targeted immunomodulator used for the treatment of Behcet's Disease as confirmed by claims history or submission of medical records [e.g., Remicade (infliximab), adalimumab, Enbrel (etanercept)]**

**AND**

**1.4 Patient is not receiving Otezla in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]**

**AND**

**1.5 Prescribed by or in consultation with ONE of the following:**

- Rheumatologist
- Dermatologist

**OR**

**2 - All of the following:**

**2.1** Patient is currently on Otezla therapy as confirmed by claims history or submission of medical records

**AND**

**2.2** Diagnosis of Behcet's Disease

**AND**

**2.3** Patient has active oral ulcers attributed to Behcet's Disease

**AND**

**2.4** Patient is not receiving Otezla in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

**AND**

**2.5** Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Dermatologist

|                     |                                                         |
|---------------------|---------------------------------------------------------|
| Product Name:Otezla |                                                         |
| Diagnosis           | Psoriatic Arthritis, Behcet's Disease, Plaque Psoriasis |
| Approval Length     | 12 month(s)                                             |
| Therapy Stage       | Reauthorization                                         |
| Guideline Type      | Prior Authorization                                     |

### Approval Criteria

1 - Documentation of positive clinical response to Otezla therapy

**AND**

2 - Patient is not receiving Otezla in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

## 2 . Revision History

| Date     | Notes                                                                                                                  |
|----------|------------------------------------------------------------------------------------------------------------------------|
| 3/3/2025 | Added NM to formulary list. Replaced Stelara with ustekinumab and updated language to state "targeted immunomodulator" |



Oxervate



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-230188                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Guideline Name</b> | Oxervate                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 5/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                        |                        |
|------------------------|------------------------|
| Product Name: Oxervate |                        |
| Diagnosis              | Neurotrophic keratitis |
| Approval Length        | 8 Week(s)              |
| Guideline Type         | Prior Authorization    |

### **Approval Criteria**

**1** - Diagnosis of Stage 2 or 3 neurotrophic keratitis

**AND**

**2** - Failure to at least ONE OTC (over the counter) ocular artificial tear product (e.g., Systane Ultra, Akwa Tears, Refresh Optive, Soothe XP) as confirmed by claims history or submission of medical records

**AND**

**3** - Prescribed by or in consultation with ONE of the following:

- Ophthalmologist
- Optometrist

## **2 . Revision History**

| Date      | Notes                 |
|-----------|-----------------------|
| 3/26/2025 | Combined formularies. |

PAH



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-396199                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Guideline Name</b> | PAH                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 10/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                                                                                                                                                                                                                                              |                                       |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|
| Product Name:Adempas, Brand Letairis, generic ambrisentan, Opsumit, generic sildenafil 20 mg, Brand Revatio tabs/susp, generic sildenafil susp, Tracleer, generic bosentan, Brand Adcirca, Alyq, generic tadalafil (PAH, generic of Adcirca) |                                       |
| Diagnosis                                                                                                                                                                                                                                    | Pulmonary Arterial Hypertension (PAH) |
| Approval Length                                                                                                                                                                                                                              | 12 month(s)                           |
| Guideline Type                                                                                                                                                                                                                               | Prior Authorization                   |

### Approval Criteria

1 - Diagnosis of pulmonary arterial hypertension (PAH)

Product Name:Liqrev, Tadliq

|                 |                                       |
|-----------------|---------------------------------------|
| Diagnosis       | Pulmonary Arterial Hypertension (PAH) |
| Approval Length | 12 month(s)                           |
| Therapy Stage   | Initial Authorization                 |
| Guideline Type  | Prior Authorization                   |

### Approval Criteria

1 - ONE of the following:

1.1 BOTH of the following:

- Pulmonary arterial hypertension is symptomatic
- Diagnosis of pulmonary arterial hypertension that is confirmed by right heart catheterization

**OR**

1.2 Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension

**AND**

2 - ONE of the following:

2.1 Failure to BOTH of the following as confirmed by claims history or submission of medical records:

2.1.1 ONE of the following:

- Adempas

- Sildenafil citrate oral suspension (generic Revatio)

**AND**

**2.1.2** An ERA (endothelin receptor antagonist) [e.g., ambrisentan (generic Letairis), Opsumit, or bosentan (generic Tracleer)]

**OR**

**2.2** History of contraindication or intolerance to BOTH of the following (please specify contraindication or intolerance):

**2.2.1** ONE of the following:

- Adempas
- Sildenafil citrate oral suspension (generic Revatio)

**AND**

**2.2.2** An ERA [e.g., ambrisentan (generic Letairis), Opsumit, or bosentan (generic Tracleer)]

|                                                                                                                                         |                                       |
|-----------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|
| Product Name: Orenitram, Tyvaso DPI, Uptravi, Yutrepia                                                                                  |                                       |
| Diagnosis                                                                                                                               | Pulmonary Arterial Hypertension (PAH) |
| Approval Length                                                                                                                         | 12 month(s)                           |
| Therapy Stage                                                                                                                           | Initial Authorization                 |
| Guideline Type                                                                                                                          | Prior Authorization                   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Both of the following:</p> <p><b>1.1</b> As continuation of therapy</p> <p><b>AND</b></p> |                                       |

**1.2** Patient is not taking the requested medication in combination with a prostanoid/prostacyclin analogue (e.g., epoprostenol, iloprost, treprostinil)

**OR**

**2** - ALL of the following:

**2.1** ONE of the following:

**2.1.1** BOTH of the following:

- Pulmonary arterial hypertension is symptomatic
- Diagnosis of pulmonary arterial hypertension that is confirmed by right heart catheterization

**OR**

**2.1.2** Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension

**AND**

**2.2** ONE of the following:

**2.2.1** Failure to BOTH of the following as confirmed by claims history or submission of medical records:

**2.2.1.1** ONE of the following:

- Adempas
- A PDE-5 inhibitor [e.g., sildenafil citrate (generic Revatio), tadalafil (generic Adcirca)]

**AND**

**2.2.1.2** An ERA (endothelin receptor antagonist) [e.g., ambrisentan (generic Letairis), Opsumit, or bosentan (generic Tracleer)]

**OR**

**2.2.2** History of contraindication or intolerance to BOTH of the following (please specify contraindication or intolerance):

**2.2.2.1** ONE of the following:

- Adempas
- A PDE-5 inhibitor [e.g., sildenafil citrate (generic Revatio), tadalafil (generic Adcirca)]

**AND**

**2.2.2.2** An ERA [e.g., ambrisentan (generic Letairis), Opsumit, or bosentan (generic Tracleer)]

**AND**

**2.3** Patient is not taking the requested medication in combination with a prostanoid/prostacyclin analogue (e.g., epoprostenol, iloprost, treprostinil)

Product Name:Opsynvi

|                 |                                       |
|-----------------|---------------------------------------|
| Diagnosis       | Pulmonary Arterial Hypertension (PAH) |
| Approval Length | 12 month(s)                           |
| Therapy Stage   | Initial Authorization                 |
| Guideline Type  | Prior Authorization                   |

### Approval Criteria

**1** - One of the following:

**1.1** Both of the following:

- Pulmonary arterial hypertension is symptomatic
- Diagnosis of pulmonary arterial hypertension that is confirmed by right heart catheterization

**OR**

**1.2** Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension

**AND**

**2** - Failure to BOTH of the following taken together as confirmed by claims history or submission of medical records:

- A PDE-5 inhibitor [e.g., sildenafil citrate (generic Revatio), tadalafil (generic Adcirca)]
- A preferred ERA [e.g., ambrisentan (generic Letairis), Opsumit, or bosentan (generic Tracleer)]

**Product Name:** Tadliq, Liquev, Opsynvi

|                 |                                       |
|-----------------|---------------------------------------|
| Diagnosis       | Pulmonary Arterial Hypertension (PAH) |
| Approval Length | 12 month(s)                           |
| Therapy Stage   | Reauthorization                       |
| Guideline Type  | Prior Authorization                   |

**Approval Criteria**

**1** - Documentation the patient is receiving clinical benefit to therapy

**Product Name:** Orenitram, Tyvaso DPI, Uptravi, Yutrepia

|                 |                                       |
|-----------------|---------------------------------------|
| Diagnosis       | Pulmonary Arterial Hypertension (PAH) |
| Approval Length | 12 month(s)                           |
| Therapy Stage   | Reauthorization                       |
| Guideline Type  | Prior Authorization                   |

**Approval Criteria**

**1** - Documentation the patient is receiving clinical benefit to therapy



**AND**

**2** - Patient is not taking the requested medication in combination with a prostanoid/prostacyclin analogue (e.g., epoprostenol, iloprost, treprostinil)

|                                                                                                                                                  |                                                       |
|--------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------|
| Product Name:Adempas                                                                                                                             |                                                       |
| Diagnosis                                                                                                                                        | Chronic Thromboembolic Pulmonary Hypertension (CTEPH) |
| Approval Length                                                                                                                                  | 12 month(s)                                           |
| Guideline Type                                                                                                                                   | Prior Authorization                                   |
| <b>Approval Criteria</b><br><br><b>1</b> - Diagnosis of inoperable or persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH) |                                                       |

|                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                  |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| Product Name:Tyvaso DPI, Yutrepia                                                                                                                                                                                                                                                                                                                                                                            |                                                                  |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                    | Pulmonary Hypertension Associated with Interstitial Lung Disease |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                              | 12 month(s)                                                      |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                | Initial Authorization                                            |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                               | Prior Authorization                                              |
| <b>Approval Criteria</b><br><br><b>1</b> - Diagnosis of pulmonary hypertension associated with interstitial lung disease [WHO (World Health Organization) group 3] confirmed by right heart catheterization<br><br><p style="text-align: center;"><b>AND</b></p> <b>2</b> - Interstitial lung disease is diagnosed based on evidence of diffuse parenchymal lung disease on computed tomography of the chest |                                                                  |

**AND**

**3** - Pulmonary hypertension is symptomatic

Product Name: Tyvaso DPI, Yutrepia

|           |                                                                  |
|-----------|------------------------------------------------------------------|
| Diagnosis | Pulmonary Hypertension Associated with Interstitial Lung Disease |
|-----------|------------------------------------------------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                 |
|---------------|-----------------|
| Therapy Stage | Reauthorization |
|---------------|-----------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

### Approval Criteria

**1** - Documentation of positive clinical response to the requested therapy (e.g., improved exercise ability)

## 2 . Revision History

| Date | Notes |
|------|-------|
|------|-------|

|           |                                       |
|-----------|---------------------------------------|
| 9/12/2025 | Added Yutrepia to the GL. Updated GPI |
|-----------|---------------------------------------|

Palforzia



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-242248                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Guideline Name</b> | Palforzia                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 7/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                        |                       |
|------------------------|-----------------------|
| Product Name:Palforzia |                       |
| Approval Length        | 12 month(s)           |
| Therapy Stage          | Initial Authorization |
| Guideline Type         | Prior Authorization   |

### **Approval Criteria**

**1** - Diagnosis and clinical history of peanut allergy as documented by BOTH of the following:

- A serum peanut-specific IgE (immunoglobulin E) level of greater than or equal to 0.35 kUA/L (kilounits of allergen/liter)
- A mean wheal diameter that is at least 3 mm (millimeters) larger than the negative control on skin-prick testing for peanut

**AND**

**2** - ONE of the following:

**2.1** BOTH of the following:

- Patient is 1 to 17 years of age
- Patient is in the initial dose escalation phase of therapy

**OR**

**2.2** BOTH of the following:

- Patient is 1 year of age and older
- Patient is in the up-dosing or maintenance phase of therapy

**AND**

**3** - Used in conjunction with a peanut-avoidant diet

**AND**

**4** - Patient does not have any of the following:

- History of eosinophilic esophagitis (EoE) or eosinophilic gastrointestinal disease
- History of severe or life-threatening episode(s) of anaphylaxis or anaphylactic shock within the past 2 months

- Severe or poorly controlled asthma

**AND**

**5** - Prescribed by or in consultation with an allergist/immunologist

**AND**

**6** - Prescriber is certified/enrolled in the Palforzia REMS (Risk Evaluation and Mitigation Strategy) Program

|                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                     |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Palforzia                                                                                                                                                                                                                                                                                                                                                                                                                                  |                     |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                         | 12 month(s)         |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                           | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                          | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of positive clinical response to Palforzia therapy</p> <p><b>AND</b></p> <p><b>2</b> - Used in conjunction with a peanut-avoidant diet</p> <p><b>AND</b></p> <p><b>3</b> - Prescribed by or in consultation with an allergist/immunologist</p> <p><b>AND</b></p> <p><b>4</b> - Prescriber is certified/enrolled in the Palforzia REMS (Risk Evaluation and Mitigation Strategy) Program</p> |                     |

## 2 . Revision History

| Date      | Notes                                    |
|-----------|------------------------------------------|
| 4/22/2025 | Updated formularies, GPIs, and age range |

Palynziq



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-451203                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Guideline Name</b> | Palynziq                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Pennsylvania (ACUPA)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 12/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                       |                       |
|-----------------------|-----------------------|
| Product Name:Palynziq |                       |
| Approval Length       | 12 month(s)           |
| Therapy Stage         | Initial Authorization |

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Prior Authorization |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of phenylketonuria (PKU)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Patient is actively on a phenylalanine-restricted diet</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - ONE of the following:</p> <p><b>3.1</b> Failure to a one- to four-week trial of sapropterin as confirmed by claims history or submission of medical records</p> <p style="text-align: center;"><b>OR</b></p> <p><b>3.2</b> History of contraindication or intolerance to sapropterin therapy (please specify contraindication or intolerance)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>4</b> - Physician attestation that the patient will not be receiving Palynziq in combination with sapropterin dihydrochloride</p> <p style="text-align: center;"><b>AND</b></p> <p><b>5</b> - Submission of medical records (e.g., chart notes, laboratory values) documenting that the patient has a blood phenylalanine concentration greater than 600 micromoles/liter</p> |                     |

|                        |             |
|------------------------|-------------|
| Product Name: Palynziq |             |
| Approval Length        | 12 month(s) |



|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                     |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Patient is actively on a phenylalanine-restricted diet</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - ONE of the following:</p> <p><b>2.1</b> Submission of medical records (e.g., chart notes, laboratory values) documenting that the patient has a blood phenylalanine concentration less than 600 micromoles/liter</p> <p style="text-align: center;"><b>OR</b></p> <p><b>2.2</b> Submission of medical records (e.g., chart notes, laboratory values) documenting that the patient has achieved a 20% reduction in blood phenylalanine concentration from pre-treatment baseline</p> <p style="text-align: center;"><b>OR</b></p> <p><b>2.3</b> Patient is in initial titration/maintenance phase of dosing regimen and dose is being titrated based on blood phenylalanine concentration response up to maximum labeled dosage of 60 milligrams once daily</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Submission of medical records (e.g., chart notes, laboratory values) documenting that the patient is not receiving Palynziq in combination with sapropterin dihydrochloride (Prescription claim history that does not show any concomitant sapropterin dihydrochloride claim within 60 days of reauthorization request may be used as documentation)</p> |                     |

## 2 . Revision History

UnitedHealthcare Community Plan of New Jersey – Clinical Pharmacy Guidelines

| Date       | Notes      |
|------------|------------|
| 11/11/2025 | Removed IN |

Panretin



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-164747                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Guideline Name</b> | Panretin                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Washington (ACUWA, ACUWAAHE, ACUWAC)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 2/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                       |                  |
|-----------------------|------------------|
| Product Name:Panretin |                  |
| Diagnosis             | Kaposi's Sarcoma |

|                                                                                                                                                                                                                                                 |                     |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Approval Length                                                                                                                                                                                                                                 | 12 month(s)         |
| Guideline Type                                                                                                                                                                                                                                  | Prior Authorization |
| <b>Approval Criteria</b><br><b>1</b> - Diagnosis of AIDS (acquired immunodeficiency syndrome)-related Kaposi's Sarcoma (KS)<br><br><p style="text-align: center;"><b>AND</b></p> <b>2</b> - Patient is not receiving systemic anti-KS treatment |                     |

|                                                                                                                                            |                          |
|--------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|
| Product Name:Panretin                                                                                                                      |                          |
| Diagnosis                                                                                                                                  | NCCN Recommended Regimen |
| Approval Length                                                                                                                            | 12 month(s)              |
| Therapy Stage                                                                                                                              | Initial Authorization    |
| Guideline Type                                                                                                                             | Prior Authorization      |
| <b>Approval Criteria</b><br><b>1</b> - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium |                          |

|                                                                                                        |                          |
|--------------------------------------------------------------------------------------------------------|--------------------------|
| Product Name:Panretin                                                                                  |                          |
| Diagnosis                                                                                              | NCCN Recommended Regimen |
| Approval Length                                                                                        | 12 month(s)              |
| Therapy Stage                                                                                          | Reauthorization          |
| Guideline Type                                                                                         | Prior Authorization      |
| <b>Approval Criteria</b><br><b>1</b> - Documentation of positive clinical response to Panretin therapy |                          |

## 2 . Revision History

| Date     | Notes                                               |
|----------|-----------------------------------------------------|
| 2/5/2025 | Added IN formulary. No change to clinical criteria. |

Pemazyre



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-160646                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Guideline Name</b> | Pemazyre                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 1/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                        |                       |
|------------------------|-----------------------|
| Product Name: Pemazyre |                       |
| Diagnosis              | Cholangiocarcinoma    |
| Approval Length        | 12 month(s)           |
| Therapy Stage          | Initial Authorization |
| Guideline Type         | Prior Authorization   |

**Approval Criteria**

**1** - Diagnosis of cholangiocarcinoma

**AND**

**2** - Disease is ONE of the following:

- Unresectable locally advanced
- Resected gross residual (R2)
- Metastatic

**AND**

**3** - Disease has presence of a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement

**AND**

**4** - Patient has been previously treated

|                                                                                                                           |                            |
|---------------------------------------------------------------------------------------------------------------------------|----------------------------|
| Product Name:Pemazyre                                                                                                     |                            |
| Diagnosis                                                                                                                 | Myeloid/Lymphoid Neoplasms |
| Approval Length                                                                                                           | 12 month(s)                |
| Therapy Stage                                                                                                             | Initial Authorization      |
| Guideline Type                                                                                                            | Prior Authorization        |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of myeloid/lymphoid/mixed lineage neoplasms with eosinophilia</p> |                            |

**AND**

**2** - Disease has presence of a fibroblast growth factor receptor 1 (FGFR1) rearrangement

|                                                                                                                        |                                                |
|------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|
| Product Name:Pemazyre                                                                                                  |                                                |
| Diagnosis                                                                                                              | Cholangiocarcinoma, Myeloid/Lymphoid Neoplasms |
| Approval Length                                                                                                        | 12 month(s)                                    |
| Therapy Stage                                                                                                          | Reauthorization                                |
| Guideline Type                                                                                                         | Prior Authorization                            |
| <b>Approval Criteria</b><br><b>1</b> - Patient does not show evidence of progressive disease while on Pemazyre therapy |                                                |

|                                                                                                                                                                        |                           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Pemazyre                                                                                                                                                  |                           |
| Diagnosis                                                                                                                                                              | NCCN Recommended Regimens |
| Approval Length                                                                                                                                                        | 12 month(s)               |
| Therapy Stage                                                                                                                                                          | Initial Authorization     |
| Guideline Type                                                                                                                                                         | Prior Authorization       |
| <b>Approval Criteria</b><br><b>1</b> - Pemazyre will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium |                           |

|                       |                           |
|-----------------------|---------------------------|
| Product Name:Pemazyre |                           |
| Diagnosis             | NCCN Recommended Regimens |
| Approval Length       | 12 month(s)               |
| Therapy Stage         | Reauthorization           |
| Guideline Type        | Prior Authorization       |



**Approval Criteria**

1 - Documentation of positive clinical response to Pemazyre therapy

**2 . Revision History**

| Date       | Notes                                   |
|------------|-----------------------------------------|
| 11/14/2024 | Updated criteria for cholangiocarcinoma |

Phexxi



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-318224                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Guideline Name</b> | Phexxi                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Arizona (ACUAZ, ACUAZEC)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State Pennsylvania (ACUPA)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 8/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                     |                     |
|---------------------|---------------------|
| Product Name:Phexxi |                     |
| Approval Length     | 12 month(s)         |
| Guideline Type      | Prior Authorization |

## **Approval Criteria**

**1** - Used for the prevention of pregnancy

**AND**

**2** - ONE of the following:

**2.1** Failure to ALL of the following methods of contraception as confirmed by claims history or submission of medical records:

- Injection (e.g., Depo-Provera)
- Oral Contraceptive [e.g., norethindrone (generic Micronor), Yaz]
- Transdermal Patch (e.g., Twirla, Xulane)
- Vaginal Contraceptive Ring (e.g., Annovera, NuvaRing)
- Diaphragm
- Cervical Cap (e.g., FemCap)
- Female Condom

**OR**

**2.2** History of intolerance or contraindication to ALL of the following methods of contraception (please document intolerance or contraindication):

- Injection (e.g., Depo-Provera)
- Oral Contraceptive [e.g., norethindrone (generic Micronor), Yaz]
- Transdermal Patch (e.g., Twirla, Xulane)
- Vaginal Contraceptive Ring (e.g., Annovera, NuvaRing)
- Diaphragm
- Cervical Cap (e.g., FemCap)
- Female Condom

**AND**

**3** - ONE of the following:

**3.1** Failure to nonoxynol-9 based spermicide as confirmed by claims history or submission of medical records

**OR**

**3.2** History of intolerance or contraindication to nonoxynol-9 based spermicide (please document intolerance or contraindication)

**AND**

**4** - Provider attests they have counseled the patient regarding higher rate of pregnancy prevention with the use of other methods of contraception (e.g., injection, oral contraception, transdermal patch, vaginal ring) compared to Phexxi

## 2 . Revision History

| Date     | Notes                                                  |
|----------|--------------------------------------------------------|
| 7/7/2025 | Combined formularies. No changes to clinical criteria. |

Piqray



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-333264                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Guideline Name</b> | Piqray                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 8/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                     |                       |
|---------------------|-----------------------|
| Product Name:Piqray |                       |
| Diagnosis           | Breast Cancer         |
| Approval Length     | 12 month(s)           |
| Therapy Stage       | Initial Authorization |

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Prior Authorization |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of breast cancer</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - ONE of the following:</p> <ul style="list-style-type: none"> <li>• Advanced</li> <li>• Metastatic</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Disease is hormone receptor (HR)-positive</p> <p style="text-align: center;"><b>AND</b></p> <p><b>4</b> - Disease is human epidermal growth factor receptor 2 (HER2)-negative</p> <p style="text-align: center;"><b>AND</b></p> <p><b>5</b> - Presence of one or more PIK3CA mutations</p> <p style="text-align: center;"><b>AND</b></p> <p><b>6</b> - Used in combination with fulvestrant</p> <p style="text-align: center;"><b>AND</b></p> <p><b>7</b> - Disease has progressed on or after an endocrine-based regimen</p> |                     |

|                                                                                                                          |                     |
|--------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Piqray                                                                                                      |                     |
| Diagnosis                                                                                                                | Breast Cancer       |
| Approval Length                                                                                                          | 12 month(s)         |
| Therapy Stage                                                                                                            | Reauthorization     |
| Guideline Type                                                                                                           | Prior Authorization |
| <b>Approval Criteria</b><br><br><b>1</b> - Patient does not show evidence of progressive disease while on Piqray therapy |                     |

|                                                                                                                                                |                           |
|------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Piqray                                                                                                                            |                           |
| Diagnosis                                                                                                                                      | NCCN Recommended Regimens |
| Approval Length                                                                                                                                | 12 month(s)               |
| Therapy Stage                                                                                                                                  | Initial Authorization     |
| Guideline Type                                                                                                                                 | Prior Authorization       |
| <b>Approval Criteria</b><br><br><b>1</b> - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium |                           |

|                                                                                                          |                           |
|----------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Piqray                                                                                      |                           |
| Diagnosis                                                                                                | NCCN Recommended Regimens |
| Approval Length                                                                                          | 12 month(s)               |
| Therapy Stage                                                                                            | Reauthorization           |
| Guideline Type                                                                                           | Prior Authorization       |
| <b>Approval Criteria</b><br><br><b>1</b> - Documentation of positive clinical response to Piqray therapy |                           |

## 2 . Revision History

| Date      | Notes                                                  |
|-----------|--------------------------------------------------------|
| 7/18/2025 | Combined formularies. No changes to clinical criteria. |



Pomalyst



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-351194                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Guideline Name</b> | Pomalyst                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 9/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                       |                       |
|-----------------------|-----------------------|
| Product Name:Pomalyst |                       |
| Diagnosis             | Multiple Myeloma      |
| Approval Length       | 12 month(s)           |
| Therapy Stage         | Initial Authorization |

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Prior Authorization |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1 - Diagnosis of multiple myeloma</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>2 - ONE of the following:</b></p> <p><b>2.1 Failure of ONE of the following, confirmed by claims history or submitted medical records:</b></p> <ul style="list-style-type: none"> <li>Immunomodulatory agent [e.g., Revlimid (lenalidomide)]</li> <li>Proteasome inhibitor [e.g., Velcade (bortezomib)]</li> <li>Anti CD-38 therapy [e.g., Darzalex (daratumumab), Sarclisa (isatuximab)]</li> </ul> <p style="text-align: center;"><b>OR</b></p> <p><b>2.2 History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication):</b></p> <ul style="list-style-type: none"> <li>Immunomodulatory agent [e.g., Revlimid (lenalidomide)]</li> <li>Proteasome inhibitor [e.g., Velcade (bortezomib)]</li> <li>Anti CD-38 therapy [e.g., Darzalex (daratumumab), Sarclisa (isatuximab)]</li> </ul> <p style="text-align: center;"><b>OR</b></p> <p><b>2.3 Induction therapy for the management of POEMS (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, skin changes) syndrome</b></p> |                     |

|                       |                                  |
|-----------------------|----------------------------------|
| Product Name:Pomalyst |                                  |
| Diagnosis             | Systemic Light Chain Amyloidosis |
| Approval Length       | 12 month(s)                      |
| Therapy Stage         | Initial Authorization            |
| Guideline Type        | Prior Authorization              |

**Approval Criteria**

1 - Diagnosis of systemic light chain amyloidosis

**AND**

2 - Used in combination with dexamethasone

Product Name:Pomalyst

|           |                |
|-----------|----------------|
| Diagnosis | Kaposi Sarcoma |
|-----------|----------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

1 - Diagnosis of HIV (human immunodeficiency virus)-negative Kaposi Sarcoma

**OR**

2 - BOTH of the following:

2.1 Diagnosis of AIDS (acquired immunodeficiency syndrome)-related Kaposi Sarcoma

**AND**

2.2 Patient is currently being treated with antiretroviral therapy (ART), confirmed by claims history or submitted medical records

Product Name:Pomalyst

|           |                      |
|-----------|----------------------|
| Diagnosis | Primary CNS Lymphoma |
|-----------|----------------------|

|                                                                                                                                                                                                                                                                                                                                                                                                  |                       |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                  | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                    | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                   | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of primary central nervous system (CNS) lymphoma</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - ONE of the following:</p> <p>2.1 Used as second-line or subsequent therapy</p> <p style="text-align: center;"><b>OR</b></p> <p>2.2 Used as induction therapy if patient is unsuitable for or intolerant to high-dose methotrexate</p> |                       |

|                                                                                                                            |                                                                                          |
|----------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------|
| Product Name:Pomalyst                                                                                                      |                                                                                          |
| Diagnosis                                                                                                                  | Multiple Myeloma, Systemic Light Chain Amyloidosis, Kaposi Sarcoma, Primary CNS Lymphoma |
| Approval Length                                                                                                            | 12 month(s)                                                                              |
| Therapy Stage                                                                                                              | Reauthorization                                                                          |
| Guideline Type                                                                                                             | Prior Authorization                                                                      |
| <p><b>Approval Criteria</b></p> <p>1 - Patient does not show evidence of progressive disease while on Pomalyst therapy</p> |                                                                                          |

|                       |                           |
|-----------------------|---------------------------|
| Product Name:Pomalyst |                           |
| Diagnosis             | NCCN Recommended Regimens |

|                                                                                                                                         |                       |
|-----------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Approval Length                                                                                                                         | 12 month(s)           |
| Therapy Stage                                                                                                                           | Initial Authorization |
| Guideline Type                                                                                                                          | Prior Authorization   |
| <b>Approval Criteria</b><br><br>1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium |                       |

|                                                                                                     |                           |
|-----------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Pomalyst                                                                               |                           |
| Diagnosis                                                                                           | NCCN Recommended Regimens |
| Approval Length                                                                                     | 12 month(s)               |
| Therapy Stage                                                                                       | Reauthorization           |
| Guideline Type                                                                                      | Prior Authorization       |
| <b>Approval Criteria</b><br><br>1 - Documentation of positive clinical response to Pomalyst therapy |                           |

## 2 . Revision History

| Date      | Notes                                           |
|-----------|-------------------------------------------------|
| 7/30/2025 | Updated formularies to add IN for eff 9/1/2025. |

PPI (Proton Pump Inhibitors)



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-161201                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Guideline Name</b> | PPI (Proton Pump Inhibitors)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 1/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                                                                                    |                     |
|------------------------------------------------------------------------------------|---------------------|
| Product Name:generic lansoprazole ODT, generic esomeprazole magnesium susp packets |                     |
| Approval Length                                                                    | 12 month(s)         |
| Guideline Type                                                                     | Prior Authorization |
| Approval Criteria                                                                  |                     |

**1** - The patient is less than 2 years of age

**OR**

**2** - ONE of the following:

**2.1** Failure to BOTH of the following, as confirmed by claims history or submission of medical records

- Lansoprazole DR capsule as sprinkle administration (generic Prevacid)
- Esomeprazole magnesium OTC capsule (generic Nexium capsule 24 HR OTC) or esomeprazole magnesium capsule (generic Nexium) as sprinkle administration

**OR**

**2.2** History of contraindication or intolerance to BOTH of the following (please specify contraindication or intolerance)

- Lansoprazole DR capsule as sprinkle administration (generic Prevacid)
- Esomeprazole magnesium OTC capsule (generic Nexium capsule 24 HR OTC) or esomeprazole magnesium capsule (generic Nexium) as sprinkle administration

Product Name:Prilosec OTC, omeprazole tabs, Brand Protonix tabs, Brand Prevacid, Prevacid 24HR, Brand Aciphex, generic rabeprazole tabs, Brand Dexilant, generic dexlansoprazole, Brand Nexium caps, Brand Nexium 24HR

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

### Approval Criteria

**1** - Failure to at least a 30 day trial of THREE of the following as confirmed by claims history or submission of medical records:

- Omeprazole capsule (generic Prilosec)
- Pantoprazole tablet (generic Protonix)
- Lansoprazole delayed release (DR) capsule (generic Prevacid)

- Esomeprazole magnesium OTC capsule (generic Nexium capsule 24 HR OTC) or esomeprazole magnesium capsule (generic Nexium)

**OR**

**2** - History of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):

- Omeprazole capsule (generic Prilosec)
- Pantoprazole tablet (generic Protonix)
- Lansoprazole DR capsule (generic Prevacid)
- Esomeprazole magnesium OTC capsule (generic Nexium capsule 24 HR OTC) or esomeprazole magnesium capsule (generic Nexium)

Product Name:Prilosec susp packets, Brand Protonix susp packets, Brand Prevacid Solutab, Brand Nexium susp packets, generic pantoprazole susp packets, Rabeprazole Sprinkle

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

### Approval Criteria

**1** - Failure to at least a 30 day trial to THREE of the following products as confirmed by claims history or submission of medical records:

- Lansoprazole DR capsule as sprinkle administration (generic Prevacid)
- Esomeprazole magnesium OTC capsule (generic Nexium capsule 24 HR OTC) or esomeprazole magnesium capsule (generic Nexium) as sprinkle administration
- Lansoprazole oral disintegrating tablet (generic Prevacid Solutab) (Prior authorization required)
- Esomeprazole magnesium granule suspension (generic Nexium granule suspension) (Prior authorization required)

**OR**

**2** - History of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):

- Lansoprazole DR capsule as sprinkle administration (generic Prevacid)



- Esomeprazole magnesium OTC capsule (generic Nexium capsule 24 HR OTC) or esomeprazole magnesium capsule (generic Nexium) as sprinkle administration
- Lansoprazole oral disintegrating tablet (generic Prevacid Solutab)
- Esomeprazole magnesium granule suspension (generic Nexium granule suspension)

Product Name:omeprazole caps, Prilosec, Prilosec OTC, omeprazole tabs, generic pantoprazole tabs/susp packets, Brand Protonix tabs/susp packets, generic lansoprazole, Brand Prevacid, Prevacid 24HR, generic lansoprazole ODT, Brand Prevacid Solutab, generic esomeprazole magnesium caps, Nexium, Brand Aciphex, generic rabeprazole, Brand Dexilant, generic esomeprazole magnesium susp packets, generic dexlansoprazole, Brand Nexium, Brand Nexium 24HR, Rabeprazole Sprinkle, generic esomeprazole magnesium tabs (OTC)

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                              |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Initial Authorization                                                                                                                                                        |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Quantity Limit                                                                                                                                                               |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - The patient did not exhibit an adequate response to treatment within the quantity limit*</p> <p style="text-align: center;"><b>OR</b></p> <p><b>2</b> - The patient has documented erosive disease*</p> <p style="text-align: center;"><b>OR</b></p> <p><b>3</b> - The patient has documented symptoms of complicated disease (e.g., dysphagia, bleeding, weight loss, choking, chest pain)*</p> <p style="text-align: center;"><b>OR</b></p> <p><b>4</b> - The patient has a pathological hypersecretory condition such as Zollinger-Ellison syndrome, Barrett's Esophagus, multiple endocrine adenomas, or systemic mastocytosis**</p> |                                                                                                                                                                              |
| Notes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | <p>Authorization will be issued based on circumstance.</p> <p>*Authorization will be issued for 8 weeks.</p> <p>**Authorization of therapy will be issued for 12 months.</p> |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                 |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|
| Product Name:omeprazole caps, Prilosec, Prilosec OTC, omeprazole tabs, generic pantoprazole tabs/susp packets, Brand Protonix tabs/susp packets, generic lansoprazole, Brand Prevacid, Prevacid 24HR, generic lansoprazole ODT, Brand Prevacid Solutab, generic esomeprazole magnesium caps, Nexium, Brand Aciphex, generic rabeprazole, Brand Dexilant, generic esomeprazole magnesium susp packets, generic dextlansoprazole, Brand Nexium, Brand Nexium 24HR, Rabeprazole Sprinkle, generic esomeprazole magnesium tabs (OTC) |                 |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 12 month(s)     |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Reauthorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Quantity Limit  |
| <p><b>Approval Criteria</b></p> <p>1 - The patient is continuing therapy for a pathological hypersecretory condition such as Zollinger-Ellison syndrome, Barrett's Esophagus, multiple adenomas, or systemic mastocytosis</p>                                                                                                                                                                                                                                                                                                    |                 |

## 2 . Revision History

| Date       | Notes                                                                                             |
|------------|---------------------------------------------------------------------------------------------------|
| 11/25/2024 | Updated guideline and criteria to reflect PDL change (esomeprazole moved to preferred without PA) |

Praluent



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-411187                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Guideline Name</b> | Praluent                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 10/3/2025 |
|-----------------|-----------|

## 1 . Criteria

|                       |                                                                                                                                        |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------|
| Product Name:Praluent |                                                                                                                                        |
| Diagnosis             | Primary Hyperlipidemia -Including Heterozygous Familial Hypercholesterolemia (HeFH) and Atherosclerotic Cardiovascular Disease (ASCVD) |
| Approval Length       | 12 month(s)                                                                                                                            |
| Therapy Stage         | Initial Authorization                                                                                                                  |
| Guideline Type        | Prior Authorization                                                                                                                    |

## **Approval Criteria**

**1 - Diagnosis of ONE of the following:**

- Heterozygous familial hypercholesterolemia (HeFH)
- Atherosclerotic cardiovascular disease (ASCVD) (e.g., acute coronary syndromes, history of myocardial infarction, stable or unstable angina, coronary or other arterial revascularization, stroke, transient ischemic attack, or peripheral arterial disease presumed to be of atherosclerotic origin)
- Primary hyperlipidemia

**AND**

**2 - Submission of medical records (e.g., chart notes, laboratory values) documenting ONE of the following (prescription claims history may be used in conjunction as documentation of medication use, dose, and duration):**

**2.1 Patient has been receiving at least 12 consecutive weeks of high-intensity statin therapy [i.e., atorvastatin 40-80 milligrams (mg), rosuvastatin 20-40 mg] and will continue to receive high intensity statin at maximally tolerated dose**

**OR**

**2.2 BOTH of the following:**

**2.2.1 Patient is unable to tolerate high-intensity statin as evidenced by ONE of the following intolerable and persistent (i.e., more than 2 weeks) symptoms:**

- Myalgia [muscle symptoms without creatine kinase (CK) elevations]
- Myositis [muscle symptoms with CK elevations less than 10 times upper limit of normal (ULN)]

**AND**

**2.2.2 Patient has been receiving at least 12 consecutive weeks of low-intensity or moderate-intensity statin therapy [i.e., atorvastatin 10-20 mg, rosuvastatin 5-10 mg, simvastatin greater than or equal to 10 mg, pravastatin greater than or equal to 10 mg, lovastatin 20-40 mg, fluvastatin XL 80 mg, fluvastatin 20-40 mg up to 40 mg twice daily, or Livalo (pitavastatin) greater than or equal to 1 mg] and will continue to receive a low-intensity or moderate-intensity statin at maximally tolerated dose**

**OR**

**2.3** Patient is unable to tolerate low- or moderate-, and high-intensity statins as evidenced by ONE of the following:

**2.3.1** ONE of the following intolerable and persistent (i.e., more than 2 weeks) symptoms for low or moderate-, and high-intensity statins:

- Myalgia (muscle symptoms without CK elevations)
- Myositis (muscle symptoms with CK elevations less than 10 times ULN)

**OR**

**2.3.2** Patient has a contraindication to all statins as documented in medical records

**OR**

**2.3.3** Patient has experienced rhabdomyolysis or muscle symptoms with statin treatment with CK elevations greater than 10 times ULN

**AND**

**3** - Submission of medical records (e.g., laboratory values) documenting LDL-C greater than or equal to 55 mg/dL

**AND**

**4** - Prescribed by ONE of the following:

- Cardiologist
- Endocrinologist
- Lipid specialist

**AND**

**5** - Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor [e.g., Repatha (evolocumab)]

**AND**

**6** - Not used in combination with Leqvio (inclisiran)

**AND**

**7** - If the request is for a non-preferred\* product, ONE of the following:

**7.1** History of failure to at least THREE preferred alternatives as confirmed by claims history or submission of medical records.\* NOTE: In instances where there are fewer than three preferred alternatives, the patient must have a history of failure to all of the preferred products.

**OR**

**7.2** History of contraindication or intolerance to THREE preferred alternatives (please specify contraindication or intolerance).\* NOTE: In instances where there are fewer than three preferred alternatives, the patient must have a history of contraindication or intolerance to all of the preferred products.

|       |                          |
|-------|--------------------------|
| Notes | *PDL links in Background |
|-------|--------------------------|

|                                                                            |                                                                                                                                        |
|----------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------|
| Product Name:Praluent                                                      |                                                                                                                                        |
| Diagnosis                                                                  | Primary Hyperlipidemia -Including Heterozygous Familial Hypercholesterolemia (HeFH) and Atherosclerotic Cardiovascular Disease (ASCVD) |
| Approval Length                                                            | 12 month(s)                                                                                                                            |
| Therapy Stage                                                              | Reauthorization                                                                                                                        |
| Guideline Type                                                             | Prior Authorization                                                                                                                    |
| <b>Approval Criteria</b><br><b>1</b> - Prescribed by ONE of the following: |                                                                                                                                        |

- Cardiologist
- Endocrinologist
- Lipid specialist

**AND**

**2** - Submission of medical records (e.g., chart notes, laboratory values) documenting low density lipoprotein cholesterol (LDL-C) reduction while on Praluent therapy

**AND**

**3** - Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor [e.g., Repatha (evolocumab)]

**AND**

**4** - Not used in combination with Leqvio (inclisiran)

| Product Name:Praluent                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Homozygous Familial Hypercholesterolemia (HoFH) |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | 12 month(s)                                     |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Initial Authorization                           |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Prior Authorization                             |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of homozygous familial hypercholesterolemia (HoFH) as confirmed by submission of medical records (e.g., chart notes, laboratory values) documenting ONE of the following:</p> <p><b>1.1</b> Submission of medical records (e.g., chart notes, laboratory values) confirming genetic confirmation of bi-allelic pathogenic/likely pathogenic variants on different chromosomes at the low-density lipoprotein receptor (LDLR), apolipoprotein B (APOB), proprotein convertase subtilisin kexin type 9 (PCSK9), or low-density lipoprotein receptor adaptor protein 1 (LDLRAP1) genes or greater than or equal to 2 such variants at different loci</p> |                                                 |

**OR**

**1.2** BOTH of the following:

**1.2.1** Untreated low density lipoprotein cholesterol (LDL-C) greater than 400mg/dL

**AND**

**1.2.2** ONE of the following:

- Xanthoma before 10 years of age
- Evidence of familial hypercholesterolemia in at least one parent

**AND**

**2** - Patient is receiving other lipid-lowering therapy confirmed by claims history or submitted medical records (e.g., statin, ezetimibe, LDL apheresis)

**AND**

**3** - Prescribed by ONE of the following:

- Cardiologist
- Endocrinologist
- Lipid specialist

**AND**

**4** - Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor [e.g., Repatha (evolocumab)]

**AND**

**5** - Not used in combination with Juxtapid (lomitapide)



**AND**

**6** - If the request is for a non-preferred\* product, ONE of the following:

**6.1** History of failure to at least THREE preferred alternatives as confirmed by claims history or submission of medical records.\* NOTE: In instances where there are fewer than three preferred alternatives, the patient must have a history of failure to all of the preferred products.

**OR**

**6.2** History of contraindication or intolerance to THREE preferred alternatives (please specify contraindication or intolerance).\* NOTE: In instances where there are fewer than three preferred alternatives, the patient must have a history of contraindication or intolerance to all of the preferred products.

|       |                          |
|-------|--------------------------|
| Notes | *PDL links in Background |
|-------|--------------------------|

Product Name:Praluent

|           |                                                 |
|-----------|-------------------------------------------------|
| Diagnosis | Homozygous Familial Hypercholesterolemia (HoFH) |
|-----------|-------------------------------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                 |
|---------------|-----------------|
| Therapy Stage | Reauthorization |
|---------------|-----------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

### Approval Criteria

**1** - Prescribed by ONE of the following:

- Cardiologist
- Endocrinologist
- Lipid specialist

**AND**

**2** - Submission of medical records (e.g., chart notes, laboratory values) documenting low density lipoprotein cholesterol (LDL-C) reduction while on Praluent therapy

**AND**

**3** - Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor [e.g., Repatha (evolocumab)]

**AND**

**4** - Not used in combination with Juxtapid (lomitapide)

## 2 . Background

### Benefit/Coverage/Program Information

#### PDL links

CO: <https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html>

HI: <https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html>

MD: <https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-cp-pharmacy.html>

NJ: <https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html>

NM: <https://www.uhcprovider.com/en/health-plans-by-state/new-mexico-health-plans/nm-comm-plan-home/nm-cp-pharmacy.html>

NY: <https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html>

PA: <https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP>

RI: <https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html>

### 3 . Revision History

| Date      | Notes                                                                          |
|-----------|--------------------------------------------------------------------------------|
| 10/3/2025 | Removed NP step referring to NP guideline and included actual NP c<br>riteria. |

Preferred Non-Solid Dosage Forms



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-333192                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Guideline Name</b> | Preferred Non-Solid Dosage Forms                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Arizona (ACUAZ, ACUAZEC)</li> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State Michigan (ACUMI)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State North Carolina (ACUNC)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Pennsylvania (ACUPA)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 8/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                 |                                     |
|-----------------|-------------------------------------|
| Diagnosis       | Requests for Non-Solid Dosage Forms |
| Approval Length | 12 month(s)                         |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Administrative |
| <p><b>Approval Criteria</b></p> <p><b>1 - ONE of the following:</b></p> <p><b>1.1</b> Requested drug must be used for an FDA (Food and Drug Administration)-approved indication</p> <p style="text-align: center;"><b>OR</b></p> <p><b>1.2</b> The use of this drug is supported by information from ONE of the following appropriate compendia of current literature:</p> <ul style="list-style-type: none"> <li>• American Hospital Formulary Service Drug Information</li> <li>• National Comprehensive Cancer Network Drugs and Biologics Compendium</li> <li>• Thomson Micromedex DrugDex</li> <li>• Clinical pharmacology</li> <li>• United States Pharmacopeia-National Formulary (USP-NF)</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>2 -</b> The drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plans' program</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3 - ONE of the following:</b></p> <p><b>3.1 BOTH of the following:</b></p> <p><b>3.1.1</b> The patient is able to swallow a solid dosage form</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3.1.2 ONE of the following:</b></p> <p><b>3.1.2.1</b> History of failure to at least THREE preferred* solid oral dosage forms as confirmed</p> |                |

by claims history or submission of medical records. NOTE: In instances where there are fewer than three preferred alternatives, the patient must have a history of failure to ALL of the preferred products.

**OR**

**3.1.2.2** History of contraindication or intolerance to THREE preferred\* solid oral dosage forms (please specify contraindication or intolerance). NOTE: In instances where there are fewer than three preferred alternatives, the patient must have a history of contraindication or intolerance to ALL of the preferred products.

**OR**

**3.1.2.3** There are no preferred formulary alternatives for the requested drug

**OR**

**3.2** Patient is unable to swallow a solid dosage form

**OR**

**3.3** Patient utilizes a feeding tube for medication administration

**OR**

**3.4** Request is for a nebulized formulation of an inhaled medication for a patient who has an inability to effectively utilize an agent in an inhaler formulation due to neuromuscular or cognitive disability, or other evidence of lack of response to the inhaled formulation supported by clinical documentation

Notes

\*See Table 1 in Background for PDL links. Prior trials of formulary/PDL alternatives must sufficiently demonstrate that the formulary/PDL alternatives are either ineffective or inappropriate at the time of the request.

## 2 . Background

**Benefit/Coverage/Program Information****Table 1. PDL Links**

|                                   |                                                                                                                                                                                                                                                                               |
|-----------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Arizona</b>                    | <a href="https://www.uhcprovider.com/en/health-plans-by-state/arizona-health-plans/az-comm-plan-home/az-cp-pharmacy.html?rfid=UHCCP">https://www.uhcprovider.com/en/health-plans-by-state/arizona-health-plans/az-comm-plan-home/az-cp-pharmacy.html?rfid=UHCCP</a>           |
| <b>Colorado</b>                   | <a href="https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html</a>                               |
| <b>Hawaii</b>                     | <a href="https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html</a>                                   |
| <b>Indiana</b>                    | <a href="https://www.uhcprovider.com/en/health-plans-by-state/indiana-health-plans/in-comm-plan-home/in-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/indiana-health-plans/in-comm-plan-home/in-cp-pharmacy.html</a>                                 |
| <b>Maryland</b>                   | <a href="https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-cp-pharmacy.html</a>                               |
| <b>Michigan</b>                   | <a href="https://www.uhcprovider.com/en/health-plans-by-state/michigan-health-plans/mi-comm-plan-home/mi-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/michigan-health-plans/mi-comm-plan-home/mi-cp-pharmacy.html</a>                               |
| <b>New Jersey</b>                 | <a href="https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html</a>                           |
| <b>New Mexico</b>                 | <a href="https://www.uhcprovider.com/en/health-plans-by-state/new-mexico-health-plans/nm-comm-plan-home/nm-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/new-mexico-health-plans/nm-comm-plan-home/nm-cp-pharmacy.html</a>                           |
| <b>New York/<br/>New York EPP</b> | <a href="https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html</a>                               |
| <b>North Carolina</b>             | <a href="https://www.uhcprovider.com/en/health-plans-by-state/north-carolina-health-plans/nc-comm-plan-home/nc-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/north-carolina-health-plans/nc-comm-plan-home/nc-cp-pharmacy.html</a>                   |
| <b>Pennsylvania<br/>CAID/CHIP</b> | <a href="https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP">https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP</a> |

**3 . Revision History**

| Date | Notes |
|------|-------|
|------|-------|

|           |                                                                                  |
|-----------|----------------------------------------------------------------------------------|
| 7/16/2025 | No clinical changes to guideline. Added IN formulary and PDL link to background. |
|-----------|----------------------------------------------------------------------------------|



Pretomanid



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-270214                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Guideline Name</b> | Pretomanid                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Pennsylvania (ACUPA)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 7/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                         |                     |
|-------------------------|---------------------|
| Product Name:Pretomanid |                     |
| Approval Length         | 12 month(s)         |
| Guideline Type          | Prior Authorization |

### Approval Criteria

1 - One of the following:

1.1 Diagnosis of pulmonary extensively drug resistant (XDR) tuberculosis (TB)

**OR**

1.2 Treatment-intolerant or nonresponsive multidrug-resistant (MDR) tuberculosis (TB)

**AND**

2 - Pretomanid will be used in combination with bedaquiline and linezolid

## 2 . Revision History

| Date      | Notes               |
|-----------|---------------------|
| 5/19/2025 | Updated formularies |

Prevymis



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-129061                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Guideline Name</b> | Prevymis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>•</li> <li>•</li> <li>•</li> <li>•</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 10/1/2023 |
|-----------------|-----------|

## 1 . Criteria

|                            |                             |
|----------------------------|-----------------------------|
| Product Name:Prevymis tabs |                             |
| Diagnosis                  | Cytomegalovirus Prophylaxis |
| Approval Length            | 9 month(s)                  |
| Guideline Type             | Prior Authorization         |

**Approval Criteria**

**1** - ALL of the following:

**1.1** Patient is a recipient of an allogeneic hematopoietic stem cell transplant

**AND**

**1.2** Patient is cytomegalovirus (CMV)-seropositive

**AND**

**1.3** Provider attests that Prevymsis will be initiated between Day 0 and Day 28 post-transplantation (before or after engraftment) and is being prescribed as prophylaxis and not treatment of CMV infection

**OR**

**2** - ALL of the following:

**2.1** Patient is a recipient of a kidney transplant

**AND**

**2.2** Patient is CMV-seronegative

**AND**

**2.3** Donor is CMV-seropositive

**AND**

**2.4** Provider attests that Prevymsis will be initiated between Day 0 and Day 7 post-

transplantation (before or after engraftment) and is being prescribed as prophylaxis and not treatment of CMV infection

## 2 . Revision History

| Date      | Notes                                                         |
|-----------|---------------------------------------------------------------|
| 7/28/2023 | Updated formularies, indication, auth duration, and criteria. |

Procysbi



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-370201                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Guideline Name</b> | Procysbi                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Pennsylvania (ACUPA)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 9/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                       |             |
|-----------------------|-------------|
| Product Name:Procysbi |             |
| Approval Length       | 12 month(s) |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                        |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------|
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Initial Authorization                                                                                                                  |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Prior Authorization                                                                                                                    |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of nephropathic cystinosis</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Patient is 1 year of age or older</p> <p style="text-align: center;"><b>AND</b></p> <p>3 - ONE of the following*:</p> <p>3.1 Failure to Cystagon as confirmed by claims history or submission of medical records</p> <p style="text-align: center;"><b>OR</b></p> <p>3.2 History of intolerance or contraindication to Cystagon (please specify intolerance or contraindication)</p> |                                                                                                                                        |
| Notes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | *UHC generally does not consider frequency of dosing and/or lack of compliance to dosing regimens, an indication of medical necessity. |

|                                                                                                            |                     |
|------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Procysbi                                                                                      |                     |
| Approval Length                                                                                            | 12 month(s)         |
| Therapy Stage                                                                                              | Reauthorization     |
| Guideline Type                                                                                             | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p>1 - Documentation of positive clinical response to Procysbi therapy</p> |                     |

## 2 . Revision History

| Date      | Notes                                            |
|-----------|--------------------------------------------------|
| 8/14/2025 | Combined formularies. Updated criteria language. |



Progesterone - Non-Oral



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-242243                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Guideline Name</b> | Progesterone - Non-Oral                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 6/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                                   |                     |
|-----------------------------------|---------------------|
| Product Name: Crinone, Endometrin |                     |
| Approval Length                   | 6 month(s)          |
| Guideline Type                    | Prior Authorization |
| Approval Criteria                 |                     |

1 - Treatment is for non-infertility use (e.g., secondary amenorrhea, reduce the risk of recurrent spontaneous preterm birth)

## 2 . Revision History

| Date      | Notes               |
|-----------|---------------------|
| 4/21/2025 | Updated formularies |

Progesterone - Oral



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-331201                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Guideline Name</b> | Progesterone - Oral                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Arizona (ACUAZ, ACUAZEC)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 8/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                                                           |                     |
|-----------------------------------------------------------|---------------------|
| Product Name: Brand Prometrium, generic progesterone caps |                     |
| Approval Length                                           | 12 month(s)         |
| Guideline Type                                            | Prior Authorization |

### Approval Criteria

1 - Diagnosis of ONE of the following:

- Amenorrhea
- Endometrial hyperplasia or prevention of endometrial hyperplasia
- Abnormal uterine or vaginal bleeding
- History of preterm birth
- Prevention of preterm delivery for current pregnancy

## 2 . Revision History

| Date      | Notes               |
|-----------|---------------------|
| 7/15/2025 | Updated formularies |

Promacta, Alvaiz



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-430197                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Guideline Name</b> | Promacta, Alvaiz                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Michigan (ACUMI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 11/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                                                           |                                       |
|-----------------------------------------------------------|---------------------------------------|
| Product Name: Brand Promacta, generic eltrombopag, Alvaiz |                                       |
| Diagnosis                                                 | Chronic Immune Thrombocytopenia (ITP) |
| Approval Length                                           | 12 month(s)                           |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                       |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1 - Diagnosis of chronic idiopathic thrombocytopenic purpura (ITP)</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>2 - ONE of the following:</b></p> <p><b>2.1</b> Failure to at least ONE of the following as confirmed by claims history or submission of medical records:</p> <ul style="list-style-type: none"> <li>• Corticosteroids</li> <li>• Immunoglobulins</li> <li>• Splenectomy</li> </ul> <p style="text-align: center;"><b>OR</b></p> <p><b>2.2</b> History of contraindication or intolerance to ALL of the following (please specify intolerance or contraindication):</p> <ul style="list-style-type: none"> <li>• Corticosteroids</li> <li>• Immunoglobulins</li> <li>• Splenectomy</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>3 - If the request is for Alvaiz, ONE of the following:</b></p> <p><b>3.1</b> Failure to eltrombopag (generic Promacta) as confirmed by claims history or submission of medical records</p> <p style="text-align: center;"><b>OR</b></p> <p><b>3.2</b> History of contraindication or intolerance to eltrombopag (generic Promacta) (please specify intolerance or contraindication)</p> |                       |

**AND**

**4** - If the request is for Promacta powder for oral suspension, ONE of the following:

**4.1** Patient is unable to ingest a solid dosage form (e.g., an oral tablet or capsule) due to ONE of the following:

- Age
- oral/motor difficulties
- dysphagia

**OR**

**4.2** Patient utilizes a feeding tube for medication administration

|                                                                                                                                    |                                       |
|------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|
| Product Name:Brand Promacta, generic eltrombopag, Alvaiz                                                                           |                                       |
| Diagnosis                                                                                                                          | Chronic Immune Thrombocytopenia (ITP) |
| Approval Length                                                                                                                    | 12 month(s)                           |
| Therapy Stage                                                                                                                      | Reauthorization                       |
| Guideline Type                                                                                                                     | Prior Authorization                   |
| <b>Approval Criteria</b><br><br><b>1</b> - Documentation of positive clinical response to Promacta (eltrombopag) or Alvaiz therapy |                                       |

|                                                          |                                                 |
|----------------------------------------------------------|-------------------------------------------------|
| Product Name:Brand Promacta, generic eltrombopag, Alvaiz |                                                 |
| Diagnosis                                                | Chronic Hepatitis C-Associated Thrombocytopenia |
| Approval Length                                          | 12 month(s)                                     |
| Therapy Stage                                            | Initial Authorization                           |
| Guideline Type                                           | Prior Authorization                             |
|                                                          |                                                 |

## **Approval Criteria**

**1** - Diagnosis of chronic hepatitis C-associated thrombocytopenia

**AND**

**2** - ONE of the following:

- Planning to initiate and maintain interferon-based treatment
- Currently receiving interferon-based treatment

**AND**

**3** - If the request is for Alvaiz, ONE of the following:

**3.1** Failure to eltrombopag (generic Promacta) as confirmed by claims history or submission of medical records

**OR**

**3.2** History of contraindication or intolerance to eltrombopag (generic Promacta) (please specify intolerance or contraindication)

**AND**

**4** - If the request is for Promacta powder for oral suspension, ONE of the following:

**4.1** Patient is unable to ingest a solid dosage form (e.g., an oral tablet or capsule) due to ONE of the following:

- Age
- oral/motor difficulties
- dysphagia

**OR**

**4.2** Patient utilizes a feeding tube for medication administration



|                                                                                                                                                                                                                                                                                       |                                                 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|
| Product Name: Brand Promacta, generic eltrombopag, Alvaiz                                                                                                                                                                                                                             |                                                 |
| Diagnosis                                                                                                                                                                                                                                                                             | Chronic Hepatitis C-Associated Thrombocytopenia |
| Approval Length                                                                                                                                                                                                                                                                       | 12 month(s)                                     |
| Therapy Stage                                                                                                                                                                                                                                                                         | Reauthorization                                 |
| Guideline Type                                                                                                                                                                                                                                                                        | Prior Authorization                             |
| <p><b>Approval Criteria</b></p> <p>1 - Documentation of positive clinical response to Promacta (eltrombopag) or Alvaiz therapy</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Patient is currently on antiviral interferon therapy for treatment of chronic hepatitis C</p> |                                                 |

|                                                                                                                                                                                                                                                                                                                                                                                                     |                       |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name: Brand Promacta, generic eltrombopag, Alvaiz                                                                                                                                                                                                                                                                                                                                           |                       |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                           | Aplastic Anemia       |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                     | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                       | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                      | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of severe aplastic anemia</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - ONE of the following:</p> <p><b>2.1</b> Used in combination with standard immunosuppressive therapy [e.g., Atgam (antithymocyte globulin equine), Thymoglobulin (antithymocyte globulin rabbit), cyclosporine]</p> <p style="text-align: center;"><b>OR</b></p> |                       |

**2.2** History of failure, contraindication, or intolerance to at least one course of immunosuppressive therapy [e.g., Atgam (antithymocyte globulin equine), Thymoglobulin (antithymocyte globulin rabbit), cyclosporine]

**AND**

**3** - If the request is for Alvaiz, ONE of the following:

**3.1** Failure to eltrombopag (generic Promacta) as confirmed by claims history or submission of medical records

**OR**

**3.2** History of contraindication or intolerance to eltrombopag (generic Promacta) (please specify intolerance or contraindication)

**AND**

**4** - If the request is for Promacta powder for oral suspension, ONE of the following:

**4.1** Patient is unable to ingest a solid dosage form (e.g., an oral tablet or capsule) due to ONE of the following:

- Age
- oral/motor difficulties
- dysphagia

**OR**

**4.2** Patient utilizes a feeding tube for medication administration

|                                                           |                     |
|-----------------------------------------------------------|---------------------|
| Product Name: Brand Promacta, generic eltrombopag, Alvaiz |                     |
| Diagnosis                                                 | Aplastic Anemia     |
| Approval Length                                           | 12 month(s)         |
| Therapy Stage                                             | Reauthorization     |
| Guideline Type                                            | Prior Authorization |

**Approval Criteria**

1 - Documentation of positive clinical response to Promacta (eltrombopag) or Alvaiz therapy

Product Name: Brand Promacta, generic eltrombopag, Alvaiz

|           |                           |
|-----------|---------------------------|
| Diagnosis | NCCN Recommended Regimens |
|-----------|---------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Brand Promacta, generic eltrombopag, Alvaiz

|           |                           |
|-----------|---------------------------|
| Diagnosis | NCCN Recommended Regimens |
|-----------|---------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                 |
|---------------|-----------------|
| Therapy Stage | Reauthorization |
|---------------|-----------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

1 - Documentation of positive clinical response to therapy

## 2 . Revision History

| Date | Notes |
|------|-------|
|------|-------|

|            |                                                                            |
|------------|----------------------------------------------------------------------------|
| 10/23/2025 | Updated formularies to include IN for eff 11/1/25. Minor cosmetic updates. |
|------------|----------------------------------------------------------------------------|

Pulmozyme



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-231200                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Guideline Name</b> | Pulmozyme                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania (ACUPA)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 5/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                        |             |
|------------------------|-------------|
| Product Name:Pulmozyme |             |
| Approval Length        | 12 month(s) |

|                                                                     |                     |
|---------------------------------------------------------------------|---------------------|
| Guideline Type                                                      | Prior Authorization |
| <b>Approval Criteria</b><br><b>1 - Diagnosis of cystic fibrosis</b> |                     |

## 2 . Revision History

| Date      | Notes                                                 |
|-----------|-------------------------------------------------------|
| 3/27/2025 | Combined formularies. No change to clinical criteria. |

Pyrukynd



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-150402                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Guideline Name</b> | Pyrukynd                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 8/1/2024 |
|-----------------|----------|

## 1 . Criteria

|                                            |                       |
|--------------------------------------------|-----------------------|
| Product Name:Pyrukynd Taper Pack, Pyrukynd |                       |
| Approval Length                            | 12 month(s)           |
| Therapy Stage                              | Initial Authorization |
| Guideline Type                             | Prior Authorization   |
|                                            |                       |

## **Approval Criteria**

**1** - Diagnosis of pyruvate kinase (PK) deficiency based on ALL of the following:

**1.1** Presence of at least 2 variant alleles in the pyruvate kinase liver and red blood cell (PKLR) gene, of which at least 1 is a missense variant

**AND**

**1.2** Patient is not homozygous for the c.1436G > A (p.R479H) variant

**AND**

**1.3** Patient does not have 2 non-missense variants (without the presence of another missense variant) in the PKLR gene

**AND**

**2** - Used for the treatment of hemolytic anemia

**AND**

**3** - ONE of the following:

**3.1** BOTH of the following:

**3.1.1** Baseline hemoglobin less than or equal to 10 grams/deciliter (g/dL)

**AND**

**3.1.2** Patient has had no more than 4 transfusions in the previous 52 weeks and no transfusions in the preceding 3-month period

**OR**

**3.2** Patient has had a minimum of 6 transfusion episodes in the preceding 52 weeks



**AND**

**4** - Prescribed by a nephrologist or hematologist

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                        |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|
| Product Name:Pyrukynd Taper Pack, Pyrukynd                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                        |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Reauthorization                                                                                                                                        |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Prior Authorization                                                                                                                                    |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - BOTH of the following*:</p> <p><b>1.1</b> Documentation of positive clinical response to Pyrukynd therapy</p> <p><b>AND</b></p> <p><b>1.2</b> Prescribed by, or in consultation with, a nephrologist or hematologist</p> <p><b>OR</b></p> <p><b>2</b> - Documentation does not provide evidence of positive clinical response to Pyrukynd therapy, allow for dose titration with discontinuation of therapy**</p> |                                                                                                                                                        |
| Notes                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <p>*If criteria is met under step 1, authorization length is 12 months.</p> <p>**If criteria is met under step 2, authorization length is 4 weeks.</p> |

## 2 . Revision History

| Date      | Notes                                                                                              |
|-----------|----------------------------------------------------------------------------------------------------|
| 7/24/2024 | Updated initial approval duration from 6 months to 12 months. Simplified reauthorization criteria. |

Qbrexza, Sofdra



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-369193                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Guideline Name</b> | Qbrexza, Sofdra                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Pennsylvania (ACUPA)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Washington (ACUWA, ACUWAAHE, ACUWAC)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 9/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                              |             |
|------------------------------|-------------|
| Product Name:Qbrexza, Sofdra |             |
| Approval Length              | 12 month(s) |

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Prior Authorization |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of primary axillary hyperhidrosis</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - ONE of the following:</p> <p><b>2.1</b> Failure to Xerac-AC as confirmed by claims history or submission of medical records</p> <p style="text-align: center;"><b>OR</b></p> <p><b>2.2</b> History of contraindication or intolerance to Xerac-AC (please specify contraindication or intolerance)</p> |                     |

## 2 . Revision History

| Date      | Notes                                                                                                                                  |
|-----------|----------------------------------------------------------------------------------------------------------------------------------------|
| 8/13/2025 | Updated guideline name. Added Sofdra as a target. Removed AZ for mulary as AZ will have it's own separate guideline with Qbrexza only. |

Qfitlia



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-402269                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Guideline Name</b> | Qfitlia                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 11/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                      |                              |
|----------------------|------------------------------|
| Product Name:Qfitlia |                              |
| Diagnosis            | Hemophilia A with Inhibitors |
| Approval Length      | 12 month(s)                  |
| Therapy Stage        | Initial Authorization        |
| Guideline Type       | Prior Authorization          |

**Approval Criteria**

1 - Diagnosis of hemophilia A

**AND**

2 - Patient has developed high-titer factor VIII inhibitors (i.e., patient has developed factor VIII inhibitors greater than or equal to 5 Bethesda units [BU])

**AND**

3 - Patient is 12 years of age or older

**AND**

4 - Qfitlia is prescribed for the prevention of bleeding episodes (i.e., routine prophylaxis)

|                                                                                                                                                                                                                                                                       |                                 |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|
| Product Name:Qfitlia                                                                                                                                                                                                                                                  |                                 |
| Diagnosis                                                                                                                                                                                                                                                             | Hemophilia A without Inhibitors |
| Approval Length                                                                                                                                                                                                                                                       | 12 month(s)                     |
| Therapy Stage                                                                                                                                                                                                                                                         | Initial Authorization           |
| Guideline Type                                                                                                                                                                                                                                                        | Prior Authorization             |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of hemophilia A</p> <p><b>AND</b></p> <p>2 - Patient has not developed high-titer factor VIII inhibitors (i.e., patient has NOT developed factor VIII inhibitors greater than or equal to 5 Bethesda units [BU])</p> |                                 |

**AND**

**3** - Patient is 12 years of age or older

**AND**

**4** - Qfitlia is prescribed for the prevention of bleeding episodes (i.e., routine prophylaxis)

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                              |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|
| Product Name:Qfitlia                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                              |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Hemophilia B with Inhibitors |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                               | 12 month(s)                  |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Initial Authorization        |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Prior Authorization          |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of hemophilia B</p> <p><b>AND</b></p> <p><b>2</b> - Patient has developed high-titer factor IX inhibitors (i.e., patient has developed factor IX inhibitors greater than or equal to 5 Bethesda units [BU])</p> <p><b>AND</b></p> <p><b>3</b> - Patient is 12 years of age or older</p> <p><b>AND</b></p> <p><b>4</b> - Qfitlia is prescribed for the prevention of bleeding episodes (i.e., routine prophylaxis)</p> |                              |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                 |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|
| Product Name:Qfitlia                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                 |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Hemophilia B without Inhibitors |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | 12 month(s)                     |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Initial Authorization           |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Prior Authorization             |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of hemophilia B</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Patient has not developed high-titer factor IX inhibitors (i.e., patient has NOT developed factor IX inhibitors greater than or equal to 5 Bethesda units [BU])</p> <p style="text-align: center;"><b>AND</b></p> <p>3 - Patient is 12 years of age or older</p> <p style="text-align: center;"><b>AND</b></p> <p>4 - Qfitlia is prescribed for the prevention of bleeding episodes (i.e., routine prophylaxis)</p> |                                 |

|                                 |                                                                                                                              |
|---------------------------------|------------------------------------------------------------------------------------------------------------------------------|
| Product Name:Qfitlia            |                                                                                                                              |
| Diagnosis                       | Hemophilia A with Inhibitors, Hemophilia A without Inhibitors, Hemophilia B with Inhibitors, Hemophilia B without Inhibitors |
| Approval Length                 | 12 month(s)                                                                                                                  |
| Therapy Stage                   | Reauthorization                                                                                                              |
| Guideline Type                  | Prior Authorization                                                                                                          |
| <p><b>Approval Criteria</b></p> |                                                                                                                              |

1 - Documentation of positive clinical response to Qfitlia therapy

## 2 . Revision History

| Date      | Notes                                                      |
|-----------|------------------------------------------------------------|
| 10/1/2025 | Updated criteria. Clarified high titer inhibitor criteria. |



Qinlock



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-398212                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Guideline Name</b> | Qinlock                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 10/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                      |                                       |
|----------------------|---------------------------------------|
| Product Name:Qinlock |                                       |
| Diagnosis            | Gastrointestinal Stromal Tumor (GIST) |
| Approval Length      | 12 month(s)                           |
| Therapy Stage        | Initial Authorization                 |

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Prior Authorization |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1 - Diagnosis of gastrointestinal stromal tumor (GIST)</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>2 - ONE of the following:</b></p> <ul style="list-style-type: none"> <li>• Gross residual disease (R2 resection)</li> <li>• Unresectable primary disease</li> <li>• Tumor rupture</li> <li>• Recurrent/Metastatic</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>3 - ONE of the following:</b></p> <p><b>3.1 History of progression on ALL of the following as confirmed by claims history or submission of medical records:</b></p> <ul style="list-style-type: none"> <li>• imatinib (generic Gleevec)</li> <li>• sunitinib (generic Sutent)</li> <li>• regorafenib (generic Stivarga)</li> </ul> <p style="text-align: center;"><b>OR</b></p> <p><b>3.2 BOTH of the following:</b></p> <ul style="list-style-type: none"> <li>• History of progression on imatinib (Gleevec) as confirmed by claims history or submission of medical records</li> <li>• History of intolerance to sunitinib (Sutent) (please specify intolerance) as confirmed by claims history or submission of medical records</li> </ul> <p style="text-align: center;"><b>OR</b></p> <p><b>3.3 ALL of the following:</b></p> |                     |

- PDGFRA exon 18 mutations that are insensitive to imatinib (Gleevec) (including PDGFRA D842V)
- History of progression on Ayvakit (avapritinib) as confirmed by claims history or submission of medical records
- History of progression on dasatinib (Sprycel) as confirmed by claims history or submission of medical records

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                       |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Qinlock                                                                                                                                                                                                                                                                                                                                                                                                                                               |                       |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Cutaneous Melanoma    |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of cutaneous melanoma</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Disease is unresectable or metastatic</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Disease progression, intolerance, and/or projected risk of progression with BRAF-targeted therapy</p> <p style="text-align: center;"><b>AND</b></p> <p><b>4</b> - Positive for activating mutations of KIT</p> |                       |

|                      |                                                           |
|----------------------|-----------------------------------------------------------|
| Product Name:Qinlock |                                                           |
| Diagnosis            | Gastrointestinal Stromal Tumor (GIST), Cutaneous Melanoma |

|                                                                                                                           |                     |
|---------------------------------------------------------------------------------------------------------------------------|---------------------|
| Approval Length                                                                                                           | 12 month(s)         |
| Therapy Stage                                                                                                             | Reauthorization     |
| Guideline Type                                                                                                            | Prior Authorization |
| <b>Approval Criteria</b><br><br><b>1</b> - Patient does not show evidence of progressive disease while on Qinlock therapy |                     |

|                                                                                                                                                |                           |
|------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Qinlock                                                                                                                           |                           |
| Diagnosis                                                                                                                                      | NCCN Recommended Regimens |
| Approval Length                                                                                                                                | 12 month(s)               |
| Therapy Stage                                                                                                                                  | Initial Authorization     |
| Guideline Type                                                                                                                                 | Prior Authorization       |
| <b>Approval Criteria</b><br><br><b>1</b> - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium |                           |

|                                                                                                           |                           |
|-----------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Qinlock                                                                                      |                           |
| Diagnosis                                                                                                 | NCCN Recommended Regimens |
| Approval Length                                                                                           | 12 month(s)               |
| Therapy Stage                                                                                             | Reauthorization           |
| Guideline Type                                                                                            | Prior Authorization       |
| <b>Approval Criteria</b><br><br><b>1</b> - Documentation of positive clinical response to Qinlock therapy |                           |

## 2 . Revision History

UnitedHealthcare Community Plan of New Jersey – Clinical Pharmacy Guidelines

| Date      | Notes                                      |
|-----------|--------------------------------------------|
| 9/16/2025 | Updated formularies. Updated GIST criteria |

Qlosi, Vuity



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-208219                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Guideline Name</b> | Qlosi, Vuity                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania (ACUPA)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 4/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                    |                       |
|--------------------|-----------------------|
| Product Name:Vuity |                       |
| Approval Length    | 12 month(s)           |
| Therapy Stage      | Initial Authorization |
| Guideline Type     | Prior Authorization   |

**Approval Criteria**

1 - Diagnosis of presbyopia

**AND**

2 - Patient is between the ages of 40 to 55

**AND**

3 - Patient is unable to use corrective lenses (e.g., glasses, contacts) (document medical rationale why patient is unable to use corrective lenses)

**AND**

4 - Prescribed by ONE of the following:

- Optometrist
- Ophthalmologist

|                                                                                                                     |                     |
|---------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Vuity                                                                                                  |                     |
| Approval Length                                                                                                     | 12 month(s)         |
| Therapy Stage                                                                                                       | Reauthorization     |
| Guideline Type                                                                                                      | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p>1 - Documentation of positive clinical response to therapy</p> <p><b>AND</b></p> |                     |

**2** - Age less than 55

**AND**

**3** - Prescribed by ONE of the following:

- Optometrist
- Ophthalmologist

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                       |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Qlosi                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                       |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of presbyopia</p> <p><b>AND</b></p> <p><b>2</b> - Patient is between the ages of 45 to 64</p> <p><b>AND</b></p> <p><b>3</b> - Patient is unable to use corrective lenses (e.g., glasses, contacts) (document medical rationale why patient is unable to use corrective lenses)</p> <p><b>AND</b></p> <p><b>4</b> - Prescribed by ONE of the following:</p> <ul style="list-style-type: none"> <li>• Optometrist</li> </ul> |                       |



- Ophthalmologist

|                                                                                                                                                                                                                                                                                                                                                                     |                     |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Qlosi                                                                                                                                                                                                                                                                                                                                                  |                     |
| Approval Length                                                                                                                                                                                                                                                                                                                                                     | 12 month(s)         |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                       | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                      | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p>1 - Documentation of positive clinical response to therapy</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Age less than 64</p> <p style="text-align: center;"><b>AND</b></p> <p>3 - Prescribed by ONE of the following:</p> <ul style="list-style-type: none"> <li>• Optometrist</li> <li>• Ophthalmologist</li> </ul> |                     |

## 2 . Revision History

| Date     | Notes                             |
|----------|-----------------------------------|
| 3/5/2025 | Updated formularies. Updated GPIs |

## Quantity Limits



### Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-128955                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Guideline Name</b> | Quantity Limits                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 10/1/2023 |
|-----------------|-----------|

## 1 . Criteria

|                                                 |                                 |
|-------------------------------------------------|---------------------------------|
| Product Name:Quantity Limit, Prescription Limit |                                 |
| Diagnosis                                       | Quantity limit review (General) |
| Approval Length                                 | 12 month(s)                     |
| Guideline Type                                  | Administrative                  |

## **Approval Criteria**

**1 - ONE of the following:**

**1.1** The requested drug must be used for an FDA (Food and Drug Administration)-approved indication

**OR**

**1.2** The use of this drug is supported by information from ONE of the following appropriate compendia of current literature:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopoeia-National Formulary (USP-NF)

**AND**

**2 - ONE of the following:**

**2.1** The drug is being prescribed within the manufacturer's published dosing guidelines

**OR**

**2.2** The request falls within dosing guidelines found in ONE of the following compendia of current literature:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopoeia-National Formulary (USP-NF)

**AND**

**3** - The requested dosage cannot be achieved using the plan accepted quantity limit of a different dose or formulation.

**AND**

**4** - The drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plans' program.

**Product Name:**Quantity Limit, Prescription Limit

|                 |                                                              |
|-----------------|--------------------------------------------------------------|
| Diagnosis       | Quantity limit review for the treatment of gender dysphoria* |
| Approval Length | 12 month(s)                                                  |
| Guideline Type  | Administrative                                               |

#### Approval Criteria

**1** - The use of this drug is supported by information from ONE of the following appropriate compendia of current literature:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopoeia-National Formulary (USP-NF)

**AND**

**2** - The drug is being prescribed for an indication that is recognized as a covered benefit by the applicable health plans' program.

|       |                                                                                                                                                                                      |
|-------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Notes | * If the above criteria are not met, then refer for clinical review by an appropriate trained professional (physician or pharmacist) based on the applicable regulatory requirement. |
|-------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

**Product Name:**Quantity Limit, Prescription Limit

|           |                                                                                              |
|-----------|----------------------------------------------------------------------------------------------|
| Diagnosis | Monthly prescription limit review for migraine therapy, benzodiazepines, or muscle relaxants |
|-----------|----------------------------------------------------------------------------------------------|

|                                                                                                                                                                     |                                                                            |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------|
| Approval Length                                                                                                                                                     | 1 month(s)                                                                 |
| Guideline Type                                                                                                                                                      | Administrative                                                             |
| <b>Approval Criteria</b><br><br>1 - Medical necessity rationale provided for why the member requires 5 or more fills of the same drug or drug class within a month. |                                                                            |
| Notes                                                                                                                                                               | *If deemed medically necessary, longer authorization duration is permitted |

|                                                                                                                                    |                                                                                                    |
|------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|
| Product Name:Quantity Limit, Prescription Limit                                                                                    |                                                                                                    |
| Diagnosis                                                                                                                          | Topical products exceeding the allowable package size per fill OR the allowable quantity per month |
| Approval Length                                                                                                                    | 12 month(s)                                                                                        |
| Guideline Type                                                                                                                     | Administrative                                                                                     |
| <b>Approval Criteria</b><br><br>1 - The physician attests that a larger quantity is needed for treatment of a larger surface area. |                                                                                                    |

## 2 . Revision History

| Date      | Notes                                                                                                  |
|-----------|--------------------------------------------------------------------------------------------------------|
| 7/25/2023 | Updated guideline name. Defined FDA and reformatted step 2 of Quantity limit review (General) section. |

Radicava ORS



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-331193                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Guideline Name</b> | Radicava ORS                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Pennsylvania (ACUPA)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 8/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                           |             |
|---------------------------|-------------|
| Product Name:Radicava ORS |             |
| Approval Length           | 12 month(s) |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                       |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1 - BOTH of the following:</b></p> <p><b>1.1</b> Patient has been established on therapy with edaravone for amyotrophic lateral sclerosis (ALS) under an active UnitedHealthcare medical benefit prior authorization</p> <p style="text-align: center;"><b>AND</b></p> <p><b>1.2</b> ALL of the following:</p> <p><b>1.2.1</b> Diagnosis of ALS</p> <p style="text-align: center;"><b>AND</b></p> <p><b>1.2.2</b> Prescribed by, or in consultation with, a neurologist with expertise in the diagnosis of ALS</p> <p style="text-align: center;"><b>AND</b></p> <p><b>1.2.3</b> Patient is currently receiving edaravone therapy</p> <p style="text-align: center;"><b>AND</b></p> <p><b>1.2.4</b> Patient is not dependent on invasive ventilation</p> <p style="text-align: center;"><b>OR</b></p> <p><b>2 - ALL of the following:</b></p> <p><b>2.1</b> Submission of medical records (e.g., chart notes, previous medical history, diagnostic testing including: imaging, nerve conduction studies, laboratory values) to support the diagnosis of ALS</p> |                       |

**AND**

**2.2** Prescribed by, or in consultation with, a neurologist with expertise in the diagnosis of ALS

**AND**

**2.3** Submission of the most recent ALS Functional Rating Scale-Revised (ALSFRS-R) score confirming that the patient has scores greater than or equal to 2 in all items of the ALSFRS-R criteria at the start of treatment

**AND**

**2.4** Submission of medical records (e.g., chart notes, laboratory values) confirming that the patient has a % forced vital capacity (%FVC) greater than or equal to 80% at the start of treatment

|                                                                                                                                                                                                                                                                                                                             |                     |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Radicava ORS                                                                                                                                                                                                                                                                                                   |                     |
| Approval Length                                                                                                                                                                                                                                                                                                             | 12 month(s)         |
| Therapy Stage                                                                                                                                                                                                                                                                                                               | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                                                                                              | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of amyotrophic lateral sclerosis (ALS)</p> <p><b>AND</b></p> <p><b>2</b> - Prescribed by, or in consultation with, a neurologist with expertise in the diagnosis of ALS</p> <p><b>AND</b></p> <p><b>3</b> - Patient is currently receiving Radicava ORS therapy</p> |                     |



**AND**

**4** - Patient is not dependent on invasive ventilation

## **2 . Revision History**

| Date      | Notes                         |
|-----------|-------------------------------|
| 7/14/2025 | Updated formularies to add IN |

Ravicti



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-224239                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Guideline Name</b> | Ravicti                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 5/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                      |                       |
|----------------------|-----------------------|
| Product Name:Ravicti |                       |
| Approval Length      | 12 month(s)           |
| Therapy Stage        | Initial Authorization |

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Prior Authorization |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of urea cycle disorders (UCDs)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Patient does not have N-acetylglutamate synthase (NAGS) deficiency</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Inadequate response to ONE of the following:</p> <ul style="list-style-type: none"> <li>• Dietary protein restriction</li> <li>• Amino acid supplementation</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>4</b> - Will be used concomitantly with dietary protein restriction and, in some cases, dietary supplements (e.g., essential amino acids, arginine, citrulline, protein-free calorie supplements)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>5</b> - ONE of the following:</p> <p><b>5.1</b> BOTH of the following:</p> <p><b>5.1.1</b> Failure to sodium phenylbutyrate (Buphenyl) as confirmed by claims history or submission of medical records*</p> <p style="text-align: center;"><b>AND</b></p> <p><b>5.1.2</b> Submission of medical records (e.g., chart notes, laboratory values) documenting ONE of the following while on sodium phenylbutyrate</p> |                     |

- Fasting ammonia level greater than 0.5 ULN
- Any ammonia level (fasting/non-fasting) above the ULN

**OR**

**5.2** History of intolerance or contraindication to sodium phenylbutyrate (Buphenyl) (please specify contraindication or intolerance)\*

**OR**

**5.3** Patient is currently on Ravicti therapy

|       |                                                                                                                                      |
|-------|--------------------------------------------------------------------------------------------------------------------------------------|
| Notes | *UHC generally does not consider frequency of dosing and/or lack of compliance to dosing regimens an indication of medical necessity |
|-------|--------------------------------------------------------------------------------------------------------------------------------------|

|                                                                                                                                                                                                                                                                                                                                                                   |                     |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name: Ravicti                                                                                                                                                                                                                                                                                                                                             |                     |
| Approval Length                                                                                                                                                                                                                                                                                                                                                   | 12 month(s)         |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                     | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                    | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of positive clinical response to Ravicti therapy</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Patient is actively on dietary protein restriction and, in some cases, dietary supplements (e.g., essential amino acids, arginine, citrulline, protein-free calorie supplements)</p> |                     |

## 2 . Revision History

|      |       |
|------|-------|
| Date | Notes |
|------|-------|

|           |                                                                                                                                                                                                                                          |
|-----------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 3/25/2025 | Updated formularies. Added verification patient does not have NAGS deficiency. Separated sodium phenylbutyrate step criteria to include a verification of treatment failure via ammonia levels and added a by pass for current utilizers |
|-----------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

Rayos



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-448246                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Guideline Name</b> | Rayos                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State Michigan (ACUMI)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 12/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                    |                     |
|--------------------|---------------------|
| Product Name:Rayos |                     |
| Approval Length    | 12 month(s)         |
| Guideline Type     | Prior Authorization |

## **Approval Criteria**

**1** - ONE of the following:

**1.1** Rayos must be used for a Food and Drug Administration (FDA)-approved indication

**OR**

**1.2** The intended use of Rayos is supported by information from ONE of the following appropriate compendia of current literature:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopoeia-National Formulary (USP-NF)

**AND**

**2** - Rayos is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plan's program

**AND**

**3** - Submission of medical records (e.g., chart notes, laboratory values) documenting an intolerance to generic prednisone tablets which is unable to be resolved with attempts to minimize the adverse effects where appropriate

**AND**

**4** - ONE of the following:

**4.1** Failure to TWO of the following as confirmed by claims history or submission of medical records:

- Dexamethasone tablet/oral solution
- Hydrocortisone tablet
- Methylprednisolone tablet

- Prednisolone tablet/oral solution

**OR**

**4.2** History of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):

- Dexamethasone tablet/oral solution
- Hydrocortisone tablet
- Methylprednisolone tablet
- Prednisolone tablet/oral solution

## 2 . Revision History

| Date       | Notes                                                  |
|------------|--------------------------------------------------------|
| 11/11/2025 | Combined formularies. No changes to clinical criteria. |



Rectiv



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-161186                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Guideline Name</b> | Rectiv                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>•</li> <li>•</li> <li>•</li> <li>•</li> <li>•</li> <li>•</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 1/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                                                                    |                                            |
|--------------------------------------------------------------------|--------------------------------------------|
| Product Name:Brand Rectiv ointment, generic nitroglycerin ointment |                                            |
| Diagnosis                                                          | Pain Associated with Chronic Anal Fissures |
| Approval Length                                                    | 12 month(s)                                |

|                                                                                                                       |                     |
|-----------------------------------------------------------------------------------------------------------------------|---------------------|
| Guideline Type                                                                                                        | Prior Authorization |
| <b>Approval Criteria</b><br><br><b>1</b> - Diagnosis of moderate to severe pain associated with chronic anal fissures |                     |

## 2 . Revision History

| Date       | Notes                                 |
|------------|---------------------------------------|
| 11/22/2024 | Added generic Nitroglycerin ointment. |

Regranex



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-242213                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Guideline Name</b> | Regranex                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania (ACUPA)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 6/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                        |                     |
|------------------------|---------------------|
| Product Name: Regranex |                     |
| Approval Length        | 6 month(s)          |
| Guideline Type         | Prior Authorization |

**Approval Criteria**

1 - Patient has a lower extremity diabetic neuropathic ulcer

**2 . Revision History**

| Date      | Notes                                                  |
|-----------|--------------------------------------------------------|
| 4/17/2025 | Combined formularies. No changes to clinical criteria. |

Relyvrio



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-210215                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Guideline Name</b> | Relyvrio                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 4/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                        |                       |
|------------------------|-----------------------|
| Product Name: Relyvrio |                       |
| Approval Length        | 6 month(s)            |
| Therapy Stage          | Initial Authorization |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                     |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Submission of medical records (e.g., chart notes, previous medical history, diagnostic testing including: imaging, nerve conduction studies, laboratory values) to support the diagnosis of amyotrophic lateral sclerosis (ALS)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Prescribed by, or in consultation with, a neurologist with expertise in the diagnosis of ALS</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Provider attestation that the patient's baseline functional ability has been documented prior to initiating treatment (e.g., speech, walking, climbing stairs, etc.)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>4</b> - Patient is not dependent on invasive ventilation or tracheostomy</p> |                     |

|                                                                                                                                                  |                     |
|--------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Relyvrio                                                                                                                            |                     |
| Approval Length                                                                                                                                  | 6 month(s)          |
| Therapy Stage                                                                                                                                    | Reauthorization     |
| Guideline Type                                                                                                                                   | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of amyotrophic lateral sclerosis (ALS)</p> <p style="text-align: center;"><b>AND</b></p> |                     |

**2** - Prescribed by, or in consultation with, a neurologist with expertise in the diagnosis of ALS

**AND**

**3** - Patient is currently receiving Relyvrio therapy

**AND**

**4** - Provider attestation that the patient has slowed disease progression from baseline

**AND**

**5** - Patient is not dependent on invasive ventilation or tracheostomy

## **2 . Revision History**

| Date     | Notes                                                                                        |
|----------|----------------------------------------------------------------------------------------------|
| 3/6/2025 | Removing PA CAID for 4/1/25, no replacement, set to default. No change to clinical criteria. |

Repatha



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-249216                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Guideline Name</b> | Repatha                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 7/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                       |                                                                                         |
|-----------------------|-----------------------------------------------------------------------------------------|
| Product Name: Repatha |                                                                                         |
| Diagnosis             | Primary Hyperlipidemia (including heterozygous familial hypercholesterolemia) and ASCVD |
| Approval Length       | 12 month(s)                                                                             |
| Therapy Stage         | Initial Authorization                                                                   |
| Guideline Type        | Prior Authorization                                                                     |



## **Approval Criteria**

**1 - ONE of the following diagnoses:**

- Heterozygous familial hypercholesterolemia (HeFH)
- Atherosclerotic cardiovascular disease (ASCVD) (e.g., acute coronary syndromes, history of myocardial infarction, stable or unstable angina, coronary or other arterial revascularization, stroke, transient ischemic attack, or peripheral arterial disease presumed to be of atherosclerotic origin)
- Primary hyperlipidemia

**AND**

**2 - Submission of medical records (e.g., chart notes, laboratory values) documenting ONE of the following (prescription claims history may be used in conjunction as documentation of medication use, dose, and duration):**

**2.1 Patient has been receiving at least 12 consecutive weeks of high-intensity statin therapy (i.e., atorvastatin 40-80 mg, rosuvastatin 20-40 mg) and will continue to receive high-intensity statin at maximally tolerated dose**

**OR**

**2.2 BOTH of the following:**

**2.2.1 Patient is unable to tolerate high-intensity statin as evidenced by ONE of the following intolerable and persistent (i.e., more than 2 weeks) symptoms:**

- Myalgia [muscle symptoms without creatine kinase (CK) elevations]
- Myositis [muscle symptoms with CK elevations less than 10 times upper limit of normal (ULN)]

**AND**

**2.2.2 Patient has been receiving at least 12 consecutive weeks of low-intensity or moderate-intensity statin therapy [i.e., atorvastatin 10-20 mg, rosuvastatin 5-10 mg, simvastatin greater than or equal to 10 mg, pravastatin greater than or equal to 10 mg, lovastatin 20-40 mg, fluvastatin XL 80 mg, fluvastatin 20-40 mg up to 40 mg twice daily or Livalo (pitavastatin) greater than or equal to 1 mg] and will continue to receive a low-intensity or moderate-intensity statin at maximally tolerated dose**

**OR**

**2.3** Patient is unable to tolerate low- or moderate-, and high-intensity statins as evidenced by ONE of the following:

**2.3.1** ONE of the following intolerable and persistent (i.e., more than 2 weeks) symptoms for low- or moderate-, and high-intensity statins:

- Myalgia (muscle symptoms without CK elevations)
- Myositis [muscle symptoms with CK elevations less than 10 times upper limit of normal (ULN)]

**OR**

**2.3.2** Patient has a contraindication to all statins as confirmed by medical records

**OR**

**2.3.3** Patient has experienced rhabdomyolysis or muscle symptoms with statin treatment with CK elevations greater than 10 times ULN

**AND**

**3** - Submission of medical records (e.g., laboratory values) documenting a LDL-C greater than or equal 55 mg/dL

**AND**

**4** - Prescribed by ONE of the following:

- Cardiologist
- Endocrinologist
- Lipid specialist

**AND**

**5** - Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor [e.g., Praluent (alirocumab)]

**AND**

**6** - Not used in combination with Leqvio (inclisiran)

**Product Name:** Repatha

|                 |                                                                                         |
|-----------------|-----------------------------------------------------------------------------------------|
| Diagnosis       | Primary Hyperlipidemia (including heterozygous familial hypercholesterolemia) and ASCVD |
| Approval Length | 12 month(s)                                                                             |
| Therapy Stage   | Reauthorization                                                                         |
| Guideline Type  | Prior Authorization                                                                     |

### Approval Criteria

**1** - Prescribed by ONE of the following:

- Cardiologist
- Endocrinologist
- Lipid specialist

**AND**

**2** - Submission of medical records (e.g. chart notes, laboratory values) documenting LDL-C (low-density lipoprotein cholesterol) reduction while on Repatha therapy

**AND**

**3** - Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor [e.g., Praluent (alirocumab)]

**AND**

**4** - Not used in combination with Leqvio (inclisiran)

**Product Name:** Repatha

|                 |                                                 |
|-----------------|-------------------------------------------------|
| Diagnosis       | Homozygous Familial Hypercholesterolemia (HoFH) |
| Approval Length | 12 month(s)                                     |
| Therapy Stage   | Initial Authorization                           |
| Guideline Type  | Prior Authorization                             |

### Approval Criteria

**1** - Diagnosis of homozygous familial hypercholesterolemia (HoFH) as confirmed by submission of medical records (e.g., chart notes, laboratory values) documenting ONE of the following:

**1.1** Genetic confirmation of bi-allelic pathogenic/likely pathogenic variants on different chromosomes at the low-density lipoprotein receptor (LDLR), apolipoprotein B (APOB), proprotein convertase subtilisin kexin type 9 (PCSK9), or low-density lipoprotein receptor adaptor protein 1 (LDLRAP1) genes or 2 or more such variants at different loci

**OR**

**1.2** BOTH of the following:

**1.2.1** Untreated LDL-C (low-density lipoprotein cholesterol) greater than 400 mg/dL

**AND**

**1.2.2** ONE of the following:

- Xanthoma before 10 years of age
- Evidence of familial hypercholesterolemia in at least one parent

**AND**

**2** - Patient is receiving other lipid-lowering therapy confirmed by claims history or submitted medical records (e.g., statin, ezetimibe, LDL apheresis)

**AND**

**3** - Prescribed by ONE of the following:

- Cardiologist
- Endocrinologist
- Lipid specialist

**AND**

**4** - Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor [e.g., Praluent (alirocumab)]

**AND**

**5** - Not used in combination with Juxtapid (lomitapide)

|                                                                                                                                                                                                                                                                                                                                                                                        |                                                 |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|
| Product Name: Repatha                                                                                                                                                                                                                                                                                                                                                                  |                                                 |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                              | Homozygous Familial Hypercholesterolemia (HoFH) |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                        | 12 month(s)                                     |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                          | Reauthorization                                 |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                         | Prior Authorization                             |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Submission of medical records (e.g., chart notes, laboratory values) documenting LDL-C (low-density lipoprotein cholesterol) reduction while on Repatha therapy</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Prescribed by ONE of the following:</p> <ul style="list-style-type: none"> <li>• Cardiologist</li> </ul> |                                                 |

- Endocrinologist
- Lipid Specialist

**AND**

**3** - Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor [e.g., Praluent (alirocumab)]

**AND**

**4** - Not used in combination with Juxtapid (lomitapide)

## 2 . Revision History

| Date      | Notes                                                              |
|-----------|--------------------------------------------------------------------|
| 4/30/2025 | Removed step through ezetimibe from primary hyperlipidemia section |

Repository Corticotropins



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-249233                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Guideline Name</b> | Repository Corticotropins                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 7/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                                  |                                        |
|----------------------------------|----------------------------------------|
| Product Name: Acthar, Cortrophin |                                        |
| Diagnosis                        | Infantile spasm (i.e., West Syndrome)* |
| Approval Length                  | 1 month(s)                             |
| Guideline Type                   | Prior Authorization                    |

|                                                                                                                                                                                           |                                                                                                                                                             |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of infantile spasms (i.e., West Syndrome)*</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Patient is less than 2 years old</p> |                                                                                                                                                             |
| Notes                                                                                                                                                                                     | *Acthar gel and Cortrophin gel are not medically necessary for treatment of acute exacerbations of multiple sclerosis. See Background for more information. |

|                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                             |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Product Name:Acthar, Cortrophin                                                                                                                                                                                                                                                                                  |                                                                                                                                                             |
| Diagnosis                                                                                                                                                                                                                                                                                                        | Opsoclonus-myoclonus syndrome (i.e., Kinsbourne Syndrome)*                                                                                                  |
| Approval Length                                                                                                                                                                                                                                                                                                  | 3 month(s)                                                                                                                                                  |
| Guideline Type                                                                                                                                                                                                                                                                                                   | Prior Authorization                                                                                                                                         |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of opsoclonus-myoclonus syndrome (i.e., Kinsbourne Syndrome)*</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - If the request is for Acthar gel, provider submits documentation of reason or special circumstance patient cannot use Cortrophin Gel</p> |                                                                                                                                                             |
| Notes                                                                                                                                                                                                                                                                                                            | *Acthar gel and Cortrophin gel are not medically necessary for treatment of acute exacerbations of multiple sclerosis. See Background for more information. |

## 2 . Background

|                                             |
|---------------------------------------------|
| <b>Benefit/Coverage/Program Information</b> |
|---------------------------------------------|



**More Information:**

The Acthar Gel and Purified Cortrophin Gel package inserts have listed other conditions in which it may be used. UHCP has determined that use of Acthar Gel and Purified Cortrophin Gel is not medically necessary for treatment of the following disorders and diseases: multiple sclerosis; rheumatic; collagen; dermatologic; allergic states; ophthalmic; respiratory; and edematous state.

### 3 . Revision History

| Date     | Notes                                                                                    |
|----------|------------------------------------------------------------------------------------------|
| 5/5/2025 | Updated GPIs to add subq products. Removed dosing requirement.<br>Updated auth durations |

Retevmo



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-164067                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Guideline Name</b> | Retevmo                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 2/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                      |                                    |
|----------------------|------------------------------------|
| Product Name:Retevmo |                                    |
| Diagnosis            | Non-Small Cell Lung Cancer (NSCLC) |
| Approval Length      | 12 month(s)                        |
| Therapy Stage        | Initial Authorization              |
| Guideline Type       | Prior Authorization                |

**Approval Criteria**

**1** - Diagnosis of non-small cell lung cancer (NSCLC)

**AND**

**2** - Disease is ONE of the following:

- Recurrent
- Advanced
- Metastatic

**AND**

**3** - Presence of RET gene fusion-positive or RET rearrangement positive tumors

Product Name:Retevmo

|           |                |
|-----------|----------------|
| Diagnosis | Thyroid Cancer |
|-----------|----------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

**1** - All of the following:

**1.1** Diagnosis of medullary thyroid cancer (MTC)

**AND**

**1.2** Disease is one of the following:

- Advanced

- Metastatic

**AND**

**1.3** Disease has presence of RET gene mutation

**AND**

**1.4** Disease requires treatment with systemic therapy

**OR**

**2** - All of the following:

**2.1** Diagnosis of thyroid cancer

**AND**

**2.2** Disease is one of the following:

- Advanced
- Metastatic

**AND**

**2.3** Disease is RET gene fusion-positive

**AND**

**2.4** Disease requires treatment with systemic therapy

**AND**

**2.5** One of the following:

- Patient is radioactive iodine-refractory
- Treatment with radioactive iodine is not appropriate

| Product Name:Retevmo                                                                                                                                                                                                                                                                                                                                            |                       |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Diagnosis                                                                                                                                                                                                                                                                                                                                                       | Histiocytic Neoplasms |
| Approval Length                                                                                                                                                                                                                                                                                                                                                 | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                   | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                  | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of ONE of the following histiocytic neoplasms:</p> <ul style="list-style-type: none"> <li>• Langerhans Cell Histiocytosis</li> <li>• Erdheim-Chester disease</li> <li>• Rosai-Dorfman disease</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p>2 - Used for RET fusion target as a single agent</p> |                       |

| Product Name:Retevmo                                                                        |                       |
|---------------------------------------------------------------------------------------------|-----------------------|
| Diagnosis                                                                                   | Solid Tumors          |
| Approval Length                                                                             | 12 month(s)           |
| Therapy Stage                                                                               | Initial Authorization |
| Guideline Type                                                                              | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Presence of RET gene fusion-positive solid tumor</p> |                       |

**AND**

**2** - Disease is one of the following:

- Recurrent
- Advanced
- Metastatic

|                                                                                                                       |                                                                                         |
|-----------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| Product Name:Retevmo                                                                                                  |                                                                                         |
| Diagnosis                                                                                                             | Non-Small Cell Lung Cancer (NSCLC), Thyroid Cancer, Histiocytic Neoplasms, Solid Tumors |
| Approval Length                                                                                                       | 12 month(s)                                                                             |
| Therapy Stage                                                                                                         | Reauthorization                                                                         |
| Guideline Type                                                                                                        | Prior Authorization                                                                     |
| <b>Approval Criteria</b><br><b>1</b> - Patient does not show evidence of progressive disease while on Retevmo therapy |                                                                                         |

|                                                                                                                                            |                           |
|--------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Retevmo                                                                                                                       |                           |
| Diagnosis                                                                                                                                  | NCCN Recommended Regimens |
| Approval Length                                                                                                                            | 12 month(s)               |
| Therapy Stage                                                                                                                              | Initial Authorization     |
| Guideline Type                                                                                                                             | Prior Authorization       |
| <b>Approval Criteria</b><br><b>1</b> - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium |                           |

|                      |
|----------------------|
| Product Name:Retevmo |
|----------------------|

|                                                                                                    |                           |
|----------------------------------------------------------------------------------------------------|---------------------------|
| Diagnosis                                                                                          | NCCN Recommended Regimens |
| Approval Length                                                                                    | 12 month(s)               |
| Therapy Stage                                                                                      | Reauthorization           |
| Guideline Type                                                                                     | Prior Authorization       |
| <b>Approval Criteria</b><br><br>1 - Documentation of positive clinical response to Retevmo therapy |                           |

## 2 . Revision History

| Date      | Notes       |
|-----------|-------------|
| 1/21/2025 | Updated GPI |

Revlimid



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-398199                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Guideline Name</b> | Revlimid                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 10/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                                                    |                       |
|----------------------------------------------------|-----------------------|
| Product Name: Brand Revlimid, generic lenalidomide |                       |
| Diagnosis                                          | Multiple Myeloma      |
| Approval Length                                    | 12 month(s)           |
| Therapy Stage                                      | Initial Authorization |



|                                                                          |                     |
|--------------------------------------------------------------------------|---------------------|
| Guideline Type                                                           | Prior Authorization |
| <b>Approval Criteria</b><br><br><b>1 - Diagnosis of multiple myeloma</b> |                     |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|
| Product Name: Brand Revlimid, generic lenalidomide                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                 |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Myelodysplastic Syndromes (MDS) |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 12 month(s)                     |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Initial Authorization           |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Prior Authorization             |
| <b>Approval Criteria</b><br><br><b>1 - Diagnosis of symptomatic anemia due to myelodysplastic syndrome (MDS) associated WITH a deletion 5q</b><br><br><p style="text-align: center;"><b>OR</b></p> <b>2 - BOTH of the following:</b><br><br><b>2.1</b> Diagnosis of symptomatic anemia due to myelodysplastic syndrome (MDS) WITHOUT deletion 5q<br><br><p style="text-align: center;"><b>AND</b></p> <b>2.2</b> ONE of the following:<br><br><b>2.2.1</b> BOTH of the following:<br><br><b>2.2.1.1</b> Ring sideroblasts greater than or equal to 15% (or greater than or equal to 5% with an SF3B1 mutation)<br><br><p style="text-align: center;"><b>AND</b></p> |                                 |

**2.2.1.2** History of failure, contraindication, or intolerance to ONE of the following:

- Rytelo (imetelstat)
- Reblozyl (luspatercept-aamt)

**OR**

**2.2.2** ALL of the following:

**2.2.2.1** Serum erythropoietin levels less than or equal to 500 mU/mL

**AND**

**2.2.2.2** Ring sideroblasts less than 15% (or less than 5% with an SF3B1 mutation)

**AND**

**2.2.2.3** Used in combination with an erythropoietin stimulating agent (ESA) [e.g., Epogen, Procrit, Retacrit (epoetin alfa)] or darbepoetin alfa

**OR**

**2.2.3** ALL of the following:

**2.2.3.1** Serum erythropoietin levels greater than 500 mU/mL

**AND**

**2.2.3.2** Ring sideroblasts less than 15% (or less than 5% with an SF3B1 mutation)

**AND**

**2.2.3.3** History of failure, contraindication, intolerance, or a poor probability of responding to immunosuppressive therapy (e.g., azacitidine, decitabine)

**OR**

**3 - BOTH of the following:**

**3.1** Diagnosis of myelodysplastic/myeloproliferative neoplasms (MDS/MPN) overlap neoplasm

**AND**

**3.2** One of the following:

- Patient has SF3B1 mutation and thrombocytosis
- Patient has ring sideroblasts and thrombocytosis (MDS/MPN-RS-T)

**Product Name:**Brand Revlimid, generic lenalidomide

|           |                  |
|-----------|------------------|
| Diagnosis | B-Cell Lymphomas |
|-----------|------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

### Approval Criteria

**1 - ONE of the following diagnoses:**

- Mantle cell lymphoma (MCL)
- Extranodal marginal zone lymphoma of nongastric sites (noncutaneous)
- Extranodal marginal zone lymphoma (EMZL) of the stomach
- Classic follicular lymphoma
- Nodal marginal zone lymphoma
- Splenic marginal zone lymphoma

**OR**

**2 - BOTH of the following:**

**2.1 ONE of the following diagnoses:**

- HIV-related B-cell lymphoma
- Diffuse large B-cell lymphoma
- High-grade B-cell lymphoma
- Histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma
- Post-transplant lymphoproliferative disorders

**AND**

**2.2 Used as second line and subsequent therapy**

|                                                                                                                                                                                                                                                                                                                                                                      |                       |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name: Brand Revlimid, generic lenalidomide                                                                                                                                                                                                                                                                                                                   |                       |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                            | Hodgkin Lymphoma      |
| Approval Length                                                                                                                                                                                                                                                                                                                                                      | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                        | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                       | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1 - Diagnosis of Hodgkin lymphoma</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>2 - Used for primary refractory disease or suspected relapse</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>3 - Patient is not a candidate for high-dose therapy and autologous stem cell rescue (HDT/ASCR)</b></p> |                       |

|                                                    |                                  |
|----------------------------------------------------|----------------------------------|
| Product Name: Brand Revlimid, generic lenalidomide |                                  |
| Diagnosis                                          | Systemic Light Chain Amyloidosis |

|                                                                                                                                                                                                                                                                                                                                                                                                                      |                       |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                      | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                        | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                       | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of systemic light chain amyloidosis</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Used in combination with ONE of the following:</p> <ul style="list-style-type: none"> <li>• Dexamethasone</li> <li>• Dexamethasone and cyclophosphamide</li> <li>• Dexamethasone and Ninlaro (ixazomib)</li> <li>• Dexamethasone and Darzalex (daratumumab)</li> </ul> |                       |

|                                                                                                                                                                                                                                                                      |                                                         |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------|
| Product Name: Brand Revlimid, generic lenalidomide                                                                                                                                                                                                                   |                                                         |
| Diagnosis                                                                                                                                                                                                                                                            | Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma |
| Approval Length                                                                                                                                                                                                                                                      | 12 month(s)                                             |
| Therapy Stage                                                                                                                                                                                                                                                        | Initial Authorization                                   |
| Guideline Type                                                                                                                                                                                                                                                       | Prior Authorization                                     |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL)</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Disease is relapsed or refractory</p> <p style="text-align: center;"><b>AND</b></p> |                                                         |

**3** - Used after prior therapy with Bruton Tyrosine Kinase (BTK) inhibitor and venetoclax-based regimens

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                       |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name: Brand Revlimid, generic lenalidomide                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                       |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | T-Cell Lymphomas      |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - BOTH of the following:</p> <p><b>1.1</b> Diagnosis of peripheral T-cell lymphoma</p> <p style="text-align: center;"><b>AND</b></p> <p><b>1.2</b> ONE of the following:</p> <ul style="list-style-type: none"> <li>• Used as initial palliative intent therapy</li> <li>• Used as second-line and subsequent therapy</li> </ul> <p style="text-align: center;"><b>OR</b></p> <p><b>2</b> - BOTH of the following:</p> <ul style="list-style-type: none"> <li>• Diagnosis of adult T-cell lymphoma</li> <li>• Used as second-line and subsequent therapy</li> </ul> <p style="text-align: center;"><b>OR</b></p> <p><b>3</b> - BOTH of the following:</p> <ul style="list-style-type: none"> <li>• Diagnosis of hepatosplenic T-cell lymphoma</li> </ul> |                       |

- Used for refractory disease after two first-line therapy regimens

|                                                                                                 |                       |
|-------------------------------------------------------------------------------------------------|-----------------------|
| Product Name: Brand Revlimid, generic lenalidomide                                              |                       |
| Diagnosis                                                                                       | Primary CNS Lymphoma  |
| Approval Length                                                                                 | 12 month(s)           |
| Therapy Stage                                                                                   | Initial Authorization |
| Guideline Type                                                                                  | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of primary central nervous system lymphoma</p> |                       |

|                                                                                                                                                                                                                                                                                                                                                                                                                                              |                       |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name: Brand Revlimid, generic lenalidomide                                                                                                                                                                                                                                                                                                                                                                                           |                       |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                    | Kaposi Sarcoma        |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                              | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                               | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - ONE of the following:</p> <p>1.1 Diagnosis of HIV-negative Kaposi Sarcoma</p> <p style="text-align: center;"><b>OR</b></p> <p>1.2 BOTH of the following:</p> <ul style="list-style-type: none"> <li>• Diagnosis of HIV-related Kaposi Sarcoma</li> <li>• Patient is currently being treated with antiretroviral therapy (ART) confirmed by claims history or submission of medical records</li> </ul> |                       |

**AND**

**2** - Disease has progressed or not responded to TWO different systemic first-line therapies (e.g., liposomal doxorubicin, sirolimus, paclitaxel)

Product Name: Brand Revlimid, generic lenalidomide

|                 |                                                      |
|-----------------|------------------------------------------------------|
| Diagnosis       | Langerhans Cell Histiocytosis, Rosai-Dorfman disease |
| Approval Length | 12 month(s)                                          |
| Therapy Stage   | Initial Authorization                                |
| Guideline Type  | Prior Authorization                                  |

**Approval Criteria**

**1** - Diagnosis of ONE of the following:

- Langerhans cell histiocytosis
- Rosai-Dorfman disease

Product Name: Brand Revlimid, generic lenalidomide

|                 |                                |
|-----------------|--------------------------------|
| Diagnosis       | Multicentric Castleman Disease |
| Approval Length | 12 month(s)                    |
| Therapy Stage   | Initial Authorization          |
| Guideline Type  | Prior Authorization            |

**Approval Criteria**

**1** - Diagnosis of multicentric Castleman disease

**AND**

**2** - One of the following:



- Progressed following treatment of relapsed/refractory disease
- Considered progressive disease

| Product Name: Brand Revlimid, generic lenalidomide                                                                         |                                                                                                                                                                                                                                                                                                                                 |
|----------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Diagnosis                                                                                                                  | Multiple Myeloma, Myelodysplastic Syndromes (MDS), B-Cell Lymphomas, Hodgkin Lymphoma, Systemic Light Chain Amyloidosis, Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma, T-Cell Lymphomas, Primary CNS Lymphomas, Kaposi Sarcoma, Langerhans Cell Histiocytosis, Rosai-Dorfman disease, Multicentric Castleman Disease |
| Approval Length                                                                                                            | 12 month(s)                                                                                                                                                                                                                                                                                                                     |
| Therapy Stage                                                                                                              | Reauthorization                                                                                                                                                                                                                                                                                                                 |
| Guideline Type                                                                                                             | Prior Authorization                                                                                                                                                                                                                                                                                                             |
| <b>Approval Criteria</b><br><br><b>1</b> - Patient does not show evidence of progressive disease while on Revlimid therapy |                                                                                                                                                                                                                                                                                                                                 |

| Product Name: Brand Revlimid, generic lenalidomide                                                                                                                                              |                                 |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|
| Diagnosis                                                                                                                                                                                       | Myelofibrosis-Associated Anemia |
| Approval Length                                                                                                                                                                                 | 12 month(s)                     |
| Therapy Stage                                                                                                                                                                                   | Initial Authorization           |
| Guideline Type                                                                                                                                                                                  | Prior Authorization             |
| <b>Approval Criteria</b><br><br><b>1</b> - Diagnosis of myelofibrosis-associated anemia<br><br><div style="text-align: center;"><b>AND</b></div><br><br><b>2</b> - Presence of del(5q) mutation |                                 |

**AND**

**3** - No symptomatic splenomegaly and/or constitutional symptoms

Product Name: Brand Revlimid, generic lenalidomide

|           |                                 |
|-----------|---------------------------------|
| Diagnosis | Myelofibrosis-Associated Anemia |
|-----------|---------------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                 |
|---------------|-----------------|
| Therapy Stage | Reauthorization |
|---------------|-----------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

**1** - Documentation of positive clinical response while on Revlimid

Product Name: Brand Revlimid, generic lenalidomide

|           |                           |
|-----------|---------------------------|
| Diagnosis | NCCN Recommended Regimens |
|-----------|---------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

**1** - Revlimid will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Brand Revlimid, generic lenalidomide

|           |                           |
|-----------|---------------------------|
| Diagnosis | NCCN Recommended Regimens |
|-----------|---------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                 |
|---------------|-----------------|
| Therapy Stage | Reauthorization |
|---------------|-----------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

1 - Documentation of positive clinical response to Revlimid therapy

**2 . Revision History**

| Date      | Notes                                                  |
|-----------|--------------------------------------------------------|
| 9/15/2025 | Updated criteria for Myelodysplastic Syndromes (MDS) . |

Revuforj



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-202195                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Guideline Name</b> | Revuforj                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Washington (ACUWA, ACUWAAHE, ACUWAC)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 4/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                       |                |
|-----------------------|----------------|
| Product Name:Revuforj |                |
| Diagnosis             | Acute Leukemia |
| Approval Length       | 12 month(s)    |

|                                                                                                                                                                                                                                                                                                              |                       |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                                                                                                                                                                                                                                                | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                               | Prior Authorization   |
| <b>Approval Criteria</b><br><br><b>1</b> - Diagnosis of acute leukemia<br><br><p style="text-align: center;"><b>AND</b></p> <b>2</b> - Disease is relapsed or refractory<br><br><p style="text-align: center;"><b>AND</b></p> <b>3</b> - Positive for lysine methyltransferase 2A gene (KMT2A) translocation |                       |

|                                                                                                                            |                     |
|----------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Revuforj                                                                                                      |                     |
| Diagnosis                                                                                                                  | Acute Leukemia      |
| Approval Length                                                                                                            | 12 month(s)         |
| Therapy Stage                                                                                                              | Reauthorization     |
| Guideline Type                                                                                                             | Prior Authorization |
| <b>Approval Criteria</b><br><br><b>1</b> - Patient does not show evidence of progressive disease while on Revuforj therapy |                     |

|                       |                           |
|-----------------------|---------------------------|
| Product Name:Revuforj |                           |
| Diagnosis             | NCCN Recommended Regimens |
| Approval Length       | 12 month(s)               |
| Therapy Stage         | Initial Authorization     |
| Guideline Type        | Prior Authorization       |

**Approval Criteria**

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

|                                                                                                            |                           |
|------------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Revuforj                                                                                      |                           |
| Diagnosis                                                                                                  | NCCN Recommended Regimens |
| Approval Length                                                                                            | 12 month(s)               |
| Therapy Stage                                                                                              | Reauthorization           |
| Guideline Type                                                                                             | Prior Authorization       |
| <p><b>Approval Criteria</b></p> <p>1 - Documentation of positive clinical response to Revuforj therapy</p> |                           |

## 2 . Revision History

| Date      | Notes        |
|-----------|--------------|
| 2/26/2025 | New program. |

Reyvow



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-241193                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Guideline Name</b> | Reyvow                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 6/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                     |                       |
|---------------------|-----------------------|
| Product Name:Reyvow |                       |
| Approval Length     | 12 month(s)           |
| Therapy Stage       | Initial Authorization |
| Guideline Type      | Prior Authorization   |
| Approval Criteria   |                       |

**1** - Used for acute treatment of migraine

**AND**

**2** - Patient is 18 years of age or older

**AND**

**3** - ONE of the following:

**3.1** Failure (after at least 3 migraine episodes and a minimum of a 30-day trial), to BOTH of the following as confirmed by claims history or submission of medical records:

**3.1.1** TWO of the following:

- eletriptan (generic Relpax)
- naratriptan (generic Amerge)
- rizatriptan (generic Maxalt/Maxalt MLT)
- sumatriptan (generic Imitrex)
- zolmitriptan (generic Zomig)

**AND**

**3.1.2** ONE of the following:

- Nurtec ODT
- Ubrelvy

**OR**

**3.2** History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication):

- eletriptan (generic Relpax)
- naratriptan (generic Amerge)
- rizatriptan (generic Maxalt/Maxalt MLT)
- sumatriptan (generic Imitrex)
- zolmitriptan (generic Zomig)
- Nurtec ODT



- Ubrelvy

**AND**

**4** - Prescriber attests to BOTH of the following:

**4.1** Patient has been informed the use of Reyvow may result in significant CNS (central nervous system) impairment, and may impact the patient's ability to drive or operate machinery for 8 hours after each dose

**AND**

**4.2** If used concurrently with a benzodiazepine or other drugs that could potentially cause CNS depression, the prescriber has acknowledged that they have completed an assessment of increased risk for sedation and other cognitive and/or neuropsychiatric adverse events

**AND**

**5** - ONE of the following:

**5.1** Patient is currently treated with ONE of the following prophylactic therapies:

- A beta-blocker (i.e., atenolol, metoprolol, nadolol, propranolol, or timolol\*)
- Candesartan (generic Atacand)\*
- A calcitonin gene-related peptide receptor (CGRP) antagonist for preventive treatment of migraine [i.e., Aimovig (erenumab)\*, Ajovy (fremanezumab), Emgality (galcanezumab), Nurtec ODT, Qulipta\*, Vyepti (eptinezumab-jjmr)\*\*]\*\*\*
- Divalproex sodium (generic Depakote/Depakote ER)
- OnabotulinumtoxinA (generic Botox)\*\*
- A serotonin-norepinephrine reuptake inhibitor [i.e., duloxetine (Cymbalta), venlafaxine (Effexor/Effexor XR)]
- Topiramate (generic Topamax)
- A tricyclic antidepressant [i.e., amitriptyline (Elavil), nortriptyline (Pamelor)]

**OR**

**5.2** Patient has less than 4 migraine days per month

**OR**

**5.3** Patient has greater than or equal to 4 migraine days per month and has contraindication or intolerance to TWO of the following prophylactic therapies:

- A beta-blocker (i.e., atenolol, metoprolol, nadolol, propranolol, or timolol\*)
- Candesartan (generic Atacand)\*
- A calcitonin gene-related peptide receptor (CGRP) antagonist for preventive treatment of migraine [i.e., Aimovig (erenumab)\*, Ajovy (fremanezumab), Emgality (galcanezumab), Nurtec ODT, Qulipta\*, Vyepti (eptinezumab-jjmr)\*\*]\*\*\*
- Divalproex sodium (generic Depakote/Depakote ER)
- OnabotulinumtoxinA (generic Botox)\*\*
- A serotonin-norepinephrine reuptake inhibitor [i.e., duloxetine (Cymbalta), venlafaxine (Effexor/Effexor XR)]
- Topiramate (generic Topamax)
- A tricyclic antidepressant [i.e., amitriptyline (Elavil), nortriptyline (Pamelor)]

**Notes**

\*Timolol, candesartan, Aimovig, and Qulipta are non-preferred  
 \*\*Vyepti and OnabotulinumtoxinA (generic Botox) are medical benefits  
 \*\*\*CGRP antagonists for preventive treatment of migraines require a prior authorization.

|                                                                                                   |                     |
|---------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Reyvow                                                                               |                     |
| Approval Length                                                                                   | 12 month(s)         |
| Therapy Stage                                                                                     | Reauthorization     |
| Guideline Type                                                                                    | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p>1 - Documentation of positive clinical response to therapy</p> |                     |

## 2 . Revision History

| Date      | Notes                                                                                |
|-----------|--------------------------------------------------------------------------------------|
| 4/10/2025 | Removed prescriber requirement. Updated operational notes for prophylactic therapies |

Rezdiffra



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-432337                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Guideline Name</b> | Rezdiffra                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Washington (ACUWA, ACUWAAHE, ACUWAC)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 12/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                        |                       |
|------------------------|-----------------------|
| Product Name:Rezdiffra |                       |
| Approval Length        | 12 month(s)           |
| Therapy Stage          | Initial Authorization |

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Prior Authorization |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of metabolic dysfunction-associated steatohepatitis (MASH) [formerly known as nonalcoholic steatohepatitis (NASH)]</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Disease is fibrosis stage F2 or F3 as confirmed by ONE of the following:</p> <p><b>2.1</b> Liver stiffness measurement (LSM) by vibration-controlled transient elastography (VCTE) (e.g., FibroScan)</p> <p style="text-align: center;"><b>OR</b></p> <p><b>2.2</b> LSM by magnetic resonance elastography (MRE)</p> <p style="text-align: center;"><b>OR</b></p> <p><b>2.3</b> Liver biopsy within the past 12 months</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Patient has received comprehensive counseling regarding lifestyle modification (e.g., dietary or caloric restriction, exercise, behavioral support, community-based program)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>4</b> - Provider attests Rezdiffra will not be initiated at the same time as Wegovy (semaglutide)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>5</b> - Prescribed by or in consultation with ONE of the following:</p> |                     |

- Endocrinologist
- Gastroenterologist
- Hepatologist

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                     |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Rezdiffra                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                     |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 12 month(s)         |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of positive clinical response to Rezdiffra therapy (e.g., improvement in or stabilization of fibrosis)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Patient has NOT progressed to cirrhosis</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Prescribed by or in consultation with ONE of the following:</p> <ul style="list-style-type: none"> <li>• Endocrinologist</li> <li>• Gastroenterologist</li> <li>• Hepatologist</li> </ul> |                     |

## 2 . Revision History

| Date      | Notes                                                                                                          |
|-----------|----------------------------------------------------------------------------------------------------------------|
| 11/5/2025 | Updated formulary to include NE for same 12/1 go-live. Inactivated G L-435220. This GL will replace GL-435220. |

Rezlidhia



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-227195                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Guideline Name</b> | Rezlidhia                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Washington (ACUWA, ACUWAAHE, ACUWAC)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 5/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                        |                              |
|------------------------|------------------------------|
| Product Name:Rezlidhia |                              |
| Diagnosis              | Acute Myeloid Leukemia (AML) |
| Approval Length        | 12 month(s)                  |

|                                                                                                                                                                                                                                                                                                                                                                               |                       |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                 | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of acute myeloid leukemia (AML)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Positive for a susceptible isocitrate dehydrogenase-1 (IDH1) mutation (e.g., R132C, R132H, R132G, R132S, R132L)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Disease is relapsed or refractory</p> |                       |

|                                                                                                                                                                                                                      |                                |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|
| Product Name:Rezlidhia                                                                                                                                                                                               |                                |
| Diagnosis                                                                                                                                                                                                            | Myelodysplastic Syndrome (MDS) |
| Approval Length                                                                                                                                                                                                      | 12 month(s)                    |
| Therapy Stage                                                                                                                                                                                                        | Initial Authorization          |
| Guideline Type                                                                                                                                                                                                       | Prior Authorization            |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of myelodysplastic syndrome (MDS)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Presence of IDH1 (isocitrate dehydrogenase-1) mutation</p> |                                |

|                        |
|------------------------|
| Product Name:Rezlidhia |
|------------------------|

|                                                                                                                         |                                                              |
|-------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------|
| Diagnosis                                                                                                               | Acute Myeloid Leukemia (AML), Myelodysplastic Syndrome (MDS) |
| Approval Length                                                                                                         | 12 month(s)                                                  |
| Therapy Stage                                                                                                           | Reauthorization                                              |
| Guideline Type                                                                                                          | Prior Authorization                                          |
| <b>Approval Criteria</b><br><b>1</b> - Patient does not show evidence of progressive disease while on Rezlidhia therapy |                                                              |

|                                                                                                                                            |                           |
|--------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Rezlidhia                                                                                                                     |                           |
| Diagnosis                                                                                                                                  | NCCN Recommended Regimens |
| Approval Length                                                                                                                            | 12 month(s)               |
| Therapy Stage                                                                                                                              | Initial Authorization     |
| Guideline Type                                                                                                                             | Prior Authorization       |
| <b>Approval Criteria</b><br><b>1</b> - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium |                           |

|                                                                                                         |                           |
|---------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Rezlidhia                                                                                  |                           |
| Diagnosis                                                                                               | NCCN Recommended Regimens |
| Approval Length                                                                                         | 12 month(s)               |
| Therapy Stage                                                                                           | Reauthorization           |
| Guideline Type                                                                                          | Prior Authorization       |
| <b>Approval Criteria</b><br><b>1</b> - Documentation of positive clinical response to Rezlidhia therapy |                           |

## 2 . Revision History



| Date      | Notes                                                  |
|-----------|--------------------------------------------------------|
| 3/25/2025 | Combined formularies. Added criteria for MDS per NCCN. |

Rezurock



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-157762                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Guideline Name</b> | Rezurock                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>•</li> <li>•</li> <li>•</li> <li>•</li> <li>•</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 12/1/2024 |
|-----------------|-----------|

## 1 . Criteria

|                       |                       |
|-----------------------|-----------------------|
| Product Name:Rezurock |                       |
| Approval Length       | 12 month(s)           |
| Therapy Stage         | Initial Authorization |

|                                                                                                                                                                                                                                                                                                                                                               |                     |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Guideline Type                                                                                                                                                                                                                                                                                                                                                | Prior Authorization |
| <b>Approval Criteria</b><br><br><b>1</b> - Diagnosis of chronic graft-versus-host disease (chronic GVHD)<br><br><p style="text-align: center;"><b>AND</b></p> <b>2</b> - History of failure of at least TWO prior lines of systemic therapy (e.g., corticosteroids, mycophenolate, tacrolimus, etc.) confirmed by claims history or submitted medical records |                     |

|                                                                                                            |                     |
|------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name: Rezurock                                                                                     |                     |
| Approval Length                                                                                            | 12 month(s)         |
| Therapy Stage                                                                                              | Reauthorization     |
| Guideline Type                                                                                             | Prior Authorization |
| <b>Approval Criteria</b><br><br><b>1</b> - Documentation of positive clinical response to Rezurock therapy |                     |

## 2 . Revision History

| Date       | Notes                                            |
|------------|--------------------------------------------------|
| 10/21/2024 | Removed age requirement in initial auth section. |

Rinvoq



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-370204                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Guideline Name</b> | Rinvoq                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 9/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                     |                           |
|---------------------|---------------------------|
| Product Name:Rinvoq |                           |
| Diagnosis           | Rheumatoid Arthritis (RA) |
| Approval Length     | 12 month(s)               |
| Therapy Stage       | Initial Authorization     |
| Guideline Type      | Prior Authorization       |

## **Approval Criteria**

**1** - Diagnosis of moderately to severely active rheumatoid arthritis (RA)

**AND**

**2** - ONE of the following:

**2.1** ALL of the following:

**2.1.1** ONE of the following:

- Failure to a 3 month trial of ONE non-biologic disease modifying anti-rheumatic drug (DMARD) (e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine) at maximally indicated doses as confirmed by claims history or submission of medical records
- History of intolerance or contraindication to ONE non-biologic DMARD (e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine) (please specify intolerance or contraindication)
- Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of rheumatoid arthritis as confirmed by claims history or submission of medical records [e.g., Enbrel (etanercept), Cimzia (certolizumab), adalimumab, Simponi (golimumab), Orencia (abatacept), Olumiant (baricitinib), Xeljanz/Xeljanz XR (tofacitinib)]

**AND**

**2.1.2** ONE of the following:

**2.1.2.1** Failure to ALL of the following as confirmed by claims history or submission of medical records:

- Enbrel (etanercept)
- One of the preferred adalimumab products\*
- Tysen (tocilizumab-aazg)

**OR**

**2.1.2.2** History of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):

- Enbrel (etanercept)
- One of the preferred adalimumab products\*
- Tyenne (tocilizumab-aazg)

**OR**

**2.1.2.3** Patient has a documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-V-TR 300.29 for specific phobia diagnostic criteria)

**AND**

**2.1.3** ONE of the following:

- Failure to Olumiant as confirmed by claims history or submission of medical records
- History of contraindication or intolerance to Olumiant (please specify contraindication or intolerance)

**OR**

**2.2** Patient is currently on Rinvoq therapy as confirmed by claims history or submission of medical records

**AND**

**3** - Patient is NOT receiving Rinvoq in combination with either of the following:

- Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib)]
- Potent immunosuppressant (e.g., azathioprine or cyclosporine)

**AND**

**4** - Prescribed by or in consultation with a rheumatologist

Notes

\*See Table 2 in Background for PDL links.

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name: Rinvoq, Rinvoq LQ                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                           |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Psoriatic Arthritis (PsA) |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 12 month(s)               |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Initial Authorization     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Prior Authorization       |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of active psoriatic arthritis</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - ONE of the following:</p> <p>2.1 BOTH of the following:</p> <p>2.1.1 ONE of the following:</p> <ul style="list-style-type: none"> <li>• Failure to a 3 month trial of methotrexate at maximally indicated dose as confirmed by claims history or submission of medical records</li> <li>• History of intolerance or contraindication to methotrexate (please specify intolerance or contraindication)</li> <li>• Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of psoriatic arthritis as confirmed by claims history or submission of medical records [e.g., Enbrel (etanercept), Cimzia (certolizumab), adalimumab, Simponi (golimumab), Orencia (abatacept), ustekinumab, Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), Cosentyx (secukinumab), Taltz (ixekizumab), Olumiant (baricitinib), Otezla (apremilast), Skyrizi (risankizumab-rzaa)]</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p>2.1.2 ONE of the following:</p> <p>2.1.2.1 BOTH of the following:</p> <p>2.1.2.1.1 ONE of the following:</p> <p>2.1.2.1.1.1 Failure to TWO of the following as confirmed by claims history or submission of medical records:</p> |                           |

- One of the preferred adalimumab products\*
- Enbrel (etanercept)
- One of the preferred ustekinumab products\*

**OR**

**2.1.2.1.1.2** History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication):

- One of the preferred adalimumab products\*
- Enbrel (etanercept)
- One of the preferred ustekinumab products\*

**AND**

**2.1.2.1.2** ONE of the following:

- Failure to Cosentyx (secukinumab) as confirmed by claims history or submission of medical records
- History of intolerance or contraindication to Cosentyx (secukinumab) (please specify intolerance or contraindication)

**OR**

**2.1.2.2** Patient has a documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-V-TR 300.29 for specific phobia diagnostic criteria)

**OR**

**2.2** Patient is currently on Rinvoq or Rinvoq LQ therapy as confirmed by claims history or submission of medical records

**AND**



**3 - Patient is NOT receiving Rinvoq or Rinvoq LQ in combination with either of the following:**

- Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Otezla (apremilast)]
- Potent immunosuppressant (e.g., azathioprine or cyclosporine)

**AND**

**4 - Prescribed by or in consultation with ONE of the following:**

- Rheumatologist
- Dermatologist

Notes

\*See Table 2 in Background for PDL links.

**Product Name:**Rinvoq

|           |                   |
|-----------|-------------------|
| Diagnosis | Atopic Dermatitis |
|-----------|-------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

### Approval Criteria

**1 - Diagnosis of moderate-to-severe chronic atopic dermatitis**

**AND**

**2 - ONE of the following:**

**2.1 BOTH of the following:**

**2.1.1 ONE of the following:**

**2.1.1.1** Failure to TWO of the following therapeutic classes of topical therapies, as confirmed by claims history or submission of medical records:

- One medium to very-high potency topical corticosteroid [e.g., mometasone furoate (generic Elocon), fluocinolone acetonide (generic Synalar), fluocinonide (generic Lidex)] (see Table 1 in Background)
- One topical calcineurin inhibitor [e.g., pimecrolimus (generic Elidel), tacrolimus (generic Protopic)]
- Eucrisa (crisaborole)

**OR**

**2.1.1.2** History of intolerance or contraindication to ALL of the following therapeutic classes of topical therapies (please specify intolerance or contraindication):

- One medium to very-high potency topical corticosteroid [e.g., mometasone furoate (generic Elocon), fluocinolone acetonide (generic Synalar), fluocinonide (generic Lidex)] (see Table 1 in Background)
- One topical calcineurin inhibitor [e.g., pimecrolimus (generic Elidel), tacrolimus (generic Protopic)]
- Eucrisa (crisaborole)

**AND**

**2.1.2** ONE of the following:

**2.1.2.1** BOTH of the following:

- Submission of medical records (e.g., chart notes, laboratory values) documenting a 3 month trial of a systemic drug product for the treatment of atopic dermatitis [e.g., Adbry (tralokinumab-ldrm), Dupixent (dupilumab), Ebglyss (lebrikizumab-lbkz), Nemluvio (nemolizumab-ilto), cyclosporine, azathioprine, methotrexate, mycophenolate mofetil, etc.]
- Physician attests that the patient was not adequately controlled with the documented systemic drug product

**OR**

**2.1.2.2** Physician attests that systemic treatment with ALL of the following FDA-approved atopic dermatitis therapies is inadvisable (document drug and contraindication rationale):

- Adbry (tralokinumab-ldrm)
- Dupixent (dupilumab)
- Ebglyss (lebrikizumab-lbkz)

- Nemluvio (nemolizumab-ilto)

**OR**

**2.1.2.3** Patient has a documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure [refer to Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition Text Revision (DSM-V-TR) 300.29 for specific phobia diagnostic criteria]

**OR**

**2.2** Patient is currently on Rinvoq therapy as confirmed by claims history or submission of medical records

**AND**

**3** - Patient is NOT receiving Rinvoq in combination with either of the following:

- Targeted immunomodulator [e.g., Adbry (tralokinumab-ldrm), Dupixent (dupilumab), Cibinqo (abrocitinib), Ebglyss (lebrikizumab-lbkz), Nemluvio (nemolizumab-ilto), Xeljanz/XR (tofacitinib), Olumiant (baricitinib), Opzelura (topical ruxolitinib)]
- Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

**AND**

**4** - Prescribed by or in consultation with ONE of the following:

- Dermatologist
- Allergist
- Immunologist

|                     |                         |
|---------------------|-------------------------|
| Product Name:Rinvoq |                         |
| Diagnosis           | Ulcerative Colitis (UC) |
| Approval Length     | 12 month(s)             |
| Therapy Stage       | Initial Authorization   |
| Guideline Type      | Prior Authorization     |

## **Approval Criteria**

**1** - Diagnosis of moderately to severely active ulcerative colitis (UC)

**AND**

**2** - ONE of the following:

**2.1** BOTH of the following:

**2.1.1** ONE of the following:

- Patient has had prior or concurrent inadequate response to a therapeutic course of oral corticosteroids and/or immunosuppressants (e.g., azathioprine, 6-mercaptopurine)
- Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of ulcerative colitis as confirmed by claims history or submission of medical records [e.g., adalimumab, Simponi (golimumab), ustekinumab, Xeljanz/XR (tofacitinib)]

**AND**

**2.1.2** ONE of the following:

**2.1.2.1** Failure to ONE of the following as confirmed by claims history or submission of medical records:

- One of the preferred adalimumab products\*
- One of the preferred ustekinumab products\*

**OR**

**2.1.2.2** History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication)

- One of the preferred adalimumab products\*
- One of the preferred ustekinumab products\*

**OR**

**2.1.2.3** Patient has a documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-V-TR 300.29 for specific phobia diagnostic criteria)

**OR**

**2.2** Patient is currently on Rinvoq therapy as confirmed by claims history or submission of medical records

**AND**

**3** - Patient is NOT receiving Rinvoq in combination with either of the following:

- Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), ustekinumab, Skyrizi (risankizumab)]
- Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

**AND**

**4** - Prescribed by or in consultation with a gastroenterologist

|       |                                           |
|-------|-------------------------------------------|
| Notes | *See Table 2 in Background for PDL links. |
|-------|-------------------------------------------|

|                                                                                                                                      |                        |
|--------------------------------------------------------------------------------------------------------------------------------------|------------------------|
| Product Name:Rinvoq                                                                                                                  |                        |
| Diagnosis                                                                                                                            | Ankylosing Spondylitis |
| Approval Length                                                                                                                      | 12 month(s)            |
| Therapy Stage                                                                                                                        | Initial Authorization  |
| Guideline Type                                                                                                                       | Prior Authorization    |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - ALL of the following:</p> <p><b>1.1</b> Diagnosis of active ankylosing spondylitis</p> |                        |

**AND**

**1.2 ONE of the following:**

- Failure to TWO NSAIDs (non-steroidal anti-inflammatory drugs) (e.g., ibuprofen, naproxen) at maximally indicated doses, each used for at least 4 weeks, as confirmed by claims history or submission of medical records
- History of intolerance or contraindication to two NSAIDs (e.g., ibuprofen, naproxen) (please specify intolerance or contraindication)
- Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of ankylosing spondylitis as confirmed by claims history or submission of medical records [e.g., Enbrel (etanercept), Cimzia (certolizumab), adalimumab, Simponi (golimumab), Xeljanz/Xeljanz XR (tofacitinib)]

**AND**

**1.3 ONE of the following:**

**1.3.1 BOTH of the following:**

**1.3.1.1 ONE of the following:**

**1.3.1.1.1** Failure to BOTH of the following as confirmed by claims history or submission of medical records:

- One of the preferred adalimumab products\*
- Enbrel (etanercept)

**OR**

**1.3.1.1.2** History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- One of the preferred adalimumab products\*
- Enbrel (etanercept)

**AND**

**1.3.1.2 ONE of the following:**

- Failure to Cosentyx (secukinumab), as confirmed by claims history or submission of medical records
- History of intolerance or contraindication to Cosentyx (secukinumab) (please specify intolerance or contraindication)

**OR**

**1.3.2** Patient has a documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-V-TR 300.29 for specific phobia diagnostic criteria)

**AND**

**1.4** Patient is NOT receiving Rinvoq in combination with either of the following:

- Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib)]
- Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

**AND**

**1.5** Prescribed by or in consultation with a rheumatologist

**OR**

**2** - ALL of the following:

**2.1** Patient is currently on Rinvoq therapy, as confirmed by claims history or submission of medical records

**AND**

**2.2** Diagnosis of active ankylosing spondylitis

**AND**

**2.3** Patient is NOT receiving Rinvoq in combination with either of the following:

- Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib)]
- Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

**AND**

**2.4** Prescribed by or in consultation with a rheumatologist

|       |                                           |
|-------|-------------------------------------------|
| Notes | *See Table 2 in Background for PDL links. |
|-------|-------------------------------------------|

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                     |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------|
| Product Name:Rinvoq                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                     |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Non-Radiographic Axial Spondyloarthritis (nr-axSpA) |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 12 month(s)                                         |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Initial Authorization                               |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Prior Authorization                                 |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of non-radiographic axial spondyloarthritis</p> <p><b>AND</b></p> <p><b>2</b> - ONE of the following:</p> <p><b>2.1</b> ALL of the following:</p> <p><b>2.1.1</b> ONE of the following:</p> <ul style="list-style-type: none"> <li>• Failure to TWO NSAIDs (non-steroidal anti-inflammatory drugs) (e.g., ibuprofen, naproxen) at maximally indicated doses, each used for at least 4 weeks, as confirmed by claims history or submission of medical records</li> <li>• History of intolerance or contraindication to TWO NSAIDs (e.g., ibuprofen, naproxen) (please specify intolerance or contraindication)</li> <li>• Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of non-radiographic axial spondyloarthritis as confirmed by claims</li> </ul> |                                                     |



history or submission of medical records [e.g., Cimzia (certolizumab), Cosentyx (secukinumab)]

**AND**

**2.1.2** ONE of the following:

**2.1.2.1** ONE of the following:

- Failure to Cosentyx (secukinumab), as confirmed by claims history or submission of medical records
- History of contraindication or intolerance to Cosentyx (secukinumab) (please specify contraindication or intolerance)

**OR**

**2.1.2.2** Patient has a documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-V-TR 300.29 for specific phobia diagnostic criteria)

**OR**

**2.2** Patient is currently on Rinvoq therapy as confirmed by claims history or submission of medical records

**AND**

**3** - Patient is NOT receiving Rinvoq in combination with either of the following:

- Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib)]
- Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

**AND**

**4** - Prescribed by or in consultation with a rheumatologist

|                      |                       |
|----------------------|-----------------------|
| Product Name: Rinvoq |                       |
| Diagnosis            | Crohn's Disease (CD)  |
| Approval Length      | 12 month(s)           |
| Therapy Stage        | Initial Authorization |
| Guideline Type       | Prior Authorization   |

  

**Approval Criteria**

1 - Diagnosis of moderately to severely active Crohn's Disease

**AND**

2 - ONE of the following:

2.1 BOTH of the following:

2.1.1 ONE of the following:

2.1.1.1 Failure to ONE of the following conventional therapy drugs or classes at maximally indicated dose confirmed by claims history or submitted medical records:

- Corticosteroids (e.g., prednisone, methylprednisolone, budesonide)
- 6-mercaptopurine (Purinethol)
- Azathioprine (Imuran)
- Methotrexate (Rheumatrex, Trexall)

**OR**

2.1.1.2 History of intolerance or contraindication to ALL of the following conventional therapy drugs or classes (please specify intolerance or contraindication)

- Corticosteroids (e.g., prednisone, methylprednisolone, budesonide)
- 6-mercaptopurine (Purinethol)
- Azathioprine (Imuran)
- Methotrexate (Rheumatrex, Trexall)

**OR**

**2.1.1.3** Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of Crohn's disease as confirmed by claims history or submission of medical records [e.g., Cimzia (certolizumab), adalimumab]

**AND**

**2.1.2** ONE of the following:

**2.1.2.1** Failure to ONE of the following as confirmed by claims history or submission of medical records:

- One of the preferred adalimumab products\*
- One of the preferred ustekinumab products\*

**OR**

**2.1.2.2** History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- One of the preferred adalimumab products\*
- One of the preferred ustekinumab products\*

**OR**

**2.2** Patient is currently on Rinvoq therapy for moderately to severely active Crohn's disease as confirmed by claims history or submitted medical records

**AND**

**3** - Patient is NOT receiving Rinvoq in combination with either of the following:

- Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), ustekinumab, Skyrizi (risankizumab)]
- Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

**AND**

|                                                                       |                                           |
|-----------------------------------------------------------------------|-------------------------------------------|
| <b>4 - Prescribed by or in consultation with a gastroenterologist</b> |                                           |
| Notes                                                                 | *See Table 2 in Background for PDL links. |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                    |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------|
| <b>Product Name: Rinvoq, Rinvoq LQ</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                    |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Polyarticular Juvenile Idiopathic Arthritis (pJIA) |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | 12 month(s)                                        |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Initial Authorization                              |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Prior Authorization                                |
| <p><b>Approval Criteria</b></p> <p><b>1 - Diagnosis of active polyarticular juvenile idiopathic arthritis</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>2 - One of the following:</b></p> <p><b>2.1 One of the following:</b></p> <p><b>2.1.1 Failure to ALL of the following as confirmed by claims history or submission of medical records</b></p> <ul style="list-style-type: none"> <li>• One of the preferred adalimumab products*</li> <li>• Enbrel (etanercept)</li> <li>• Tyenne (tocilizumab-aazg)</li> </ul> <p style="text-align: center;"><b>OR</b></p> <p><b>2.1.2 History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication):</b></p> <ul style="list-style-type: none"> <li>• One of the preferred adalimumab products*</li> <li>• Enbrel (etanercept)</li> <li>• Tyenne (tocilizumab-aazg)</li> </ul> |                                                    |

**OR**

**2.2** Patient has a documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-V-TR 300.29 for specific phobia diagnostic criteria)

**OR**

**2.3** Patient is currently on Rinvoq or Rinvoq LQ therapy as confirmed by claims history or submission of medical records

**AND**

**3** - Patient is not receiving Rinvoq or Rinvoq LQ in combination with either of the following:

- Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Olumiant (baricitinib), Xeljanz (tofacitinib)]
- Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

**AND**

**4** - Prescribed by or in consultation with a rheumatologist

|       |                                           |
|-------|-------------------------------------------|
| Notes | *See Table 2 in Background for PDL links. |
|-------|-------------------------------------------|

|                     |                                                                                                                                                       |
|---------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------|
| Product Name:Rinvoq |                                                                                                                                                       |
| Diagnosis           | Rheumatoid Arthritis (RA), Ulcerative Colitis (UC), Ankylosing Spondylitis, Non-Radiographic Axial Spondyloarthritis (nr-axSpA), Crohn's Disease (CD) |
| Approval Length     | 12 month(s)                                                                                                                                           |
| Therapy Stage       | Reauthorization                                                                                                                                       |
| Guideline Type      | Prior Authorization                                                                                                                                   |
| Approval Criteria   |                                                                                                                                                       |

**1 - Documentation of positive clinical response to Rinvoq therapy**

**AND**

**2 - Patient is NOT receiving Rinvoq in combination with either of the following:**

- Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Otezla (apremilast)]\*
- Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)\*

Notes

\* Examples of drug(s) may not be applicable based on the requested indication.

**Product Name: Rinvoq, Rinvoq LQ**

|           |                                                                               |
|-----------|-------------------------------------------------------------------------------|
| Diagnosis | Psoriatic Arthritis (PsA), Polyarticular Juvenile Idiopathic Arthritis (pJIA) |
|-----------|-------------------------------------------------------------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                 |
|---------------|-----------------|
| Therapy Stage | Reauthorization |
|---------------|-----------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

### Approval Criteria

**1 - Documentation of positive clinical response to Rinvoq or Rinvoq LQ therapy**

**AND**

**2 - Patient is NOT receiving Rinvoq or Rinvoq LQ in combination with either of the following:**

- Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Otezla (apremilast)]\*
- Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)\*

|       |                                                                                |
|-------|--------------------------------------------------------------------------------|
| Notes | * Examples of drug(s) may not be applicable based on the requested indication. |
|-------|--------------------------------------------------------------------------------|

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                     |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name: Rinvoq                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                     |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Atopic Dermatitis   |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 12 month(s)         |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of positive clinical response to Rinvoq therapy</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Patient is NOT receiving Rinvoq in combination with either of the following:</p> <ul style="list-style-type: none"> <li>Targeted immunomodulator [e.g., Adbry (tralokinumab-ldrm), Dupixent (dupilumab), Cibinqo (abrocitinib), Ebglyss (lebrikizumab-lbkz), Nemluvio (nemolizumab-ilto), Xeljanz/XR (tofacitinib), Olumiant (baricitinib), Opzelura (topical ruxolitinib)]</li> <li>Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Prescribed by or in consultation with ONE of the following:</p> <ul style="list-style-type: none"> <li>Dermatologist</li> <li>Allergist</li> <li>Immunologist</li> </ul> |                     |

|                      |                            |
|----------------------|----------------------------|
| Product Name: Rinvoq |                            |
| Diagnosis            | Giant Cell Arteritis (GCA) |
| Approval Length      | 12 month(s)                |
| Therapy Stage        | Initial Authorization      |

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Prior Authorization |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1 - Diagnosis of giant cell arteritis</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>2 - One of the following:</b></p> <p><b>2.1</b> Failure to one glucocorticoid (e.g., prednisone) confirmed by claims history or submitted medical records</p> <p style="text-align: center;"><b>OR</b></p> <p><b>2.2</b> History of intolerance or contraindication to all glucocorticoids (e.g., prednisone) (please specify intolerance or contraindication)</p> <p style="text-align: center;"><b>OR</b></p> <p><b>2.3</b> Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of giant cell arteritis as confirmed by claims history or submission of medical records [e.g., tocilizumab]</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3 - One of the following:</b></p> <p><b>3.1</b> One of the following:</p> <ul style="list-style-type: none"> <li>• Failure to Tyenne (tocilizumab-aazg) as confirmed by claims history or submission of medical records</li> <li>• History of intolerance or contraindication to Tyenne (tocilizumab-aazg) (please specify intolerance or contraindication)</li> </ul> <p style="text-align: center;"><b>OR</b></p> |                     |



**3.2** Patient has a documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-V-TR 300.29 for specific phobia diagnostic criteria)

**OR**

**3.3** Patient is currently on Rinvoq or Rinvoq LQ therapy as confirmed by claims history or submission of medical records

**AND**

**4** - Patient is not receiving Rinvoq in combination with either of the following:

- Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Olumiant (baricitinib), tocilizumab, Xeljanz (tofacitinib)]
- Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

**AND**

**5** - Prescribed by or in consultation with a rheumatologist

|                                                                                                                                   |                            |
|-----------------------------------------------------------------------------------------------------------------------------------|----------------------------|
| Product Name:Rinvoq                                                                                                               |                            |
| Diagnosis                                                                                                                         | Giant Cell Arteritis (GCA) |
| Approval Length                                                                                                                   | 12 month(s)                |
| Therapy Stage                                                                                                                     | Reauthorization            |
| Guideline Type                                                                                                                    | Prior Authorization        |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of positive clinical response to Rinvoq therapy</p> <p><b>AND</b></p> |                            |

2 - Patient is NOT receiving Rinvoq in combination with either of the following:

- Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Olumiant (baricitinib), tocilizumab, Xeljanz (tofacitinib)]
- Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

## 2 . Background

| Benefit/Coverage/Program Information                   |                                             |                                        |                     |
|--------------------------------------------------------|---------------------------------------------|----------------------------------------|---------------------|
| Table 1: Relative potencies of topical corticosteroids |                                             |                                        |                     |
| <u>Class</u>                                           | <u>Drug</u>                                 | <u>Dosage Form</u>                     | <u>Strength (%)</u> |
| <u>Very high potency</u>                               | <u>Augmented betamethasone dipropionate</u> | <u>Ointment, gel</u>                   | <u>0.05</u>         |
|                                                        | <u>Clobetasol propionate</u>                | <u>Cream, foam, ointment</u>           | <u>0.05</u>         |
|                                                        | <u>Diflorasone diacetate</u>                | <u>Ointment</u>                        | <u>0.05</u>         |
|                                                        | <u>Halobetasol propionate</u>               | <u>Cream, ointment</u>                 | <u>0.05</u>         |
| <u>High Potency</u>                                    | <u>Amcinonide</u>                           | <u>Cream, lotion, ointment</u>         | <u>0.1</u>          |
|                                                        | <u>Augmented betamethasone dipropionate</u> | <u>Cream, lotion</u>                   | <u>0.05</u>         |
|                                                        | <u>Betamethasone dipropionate</u>           | <u>Cream, foam, ointment, solution</u> | <u>0.05</u>         |
|                                                        | <u>Desoximetasone</u>                       | <u>Cream, ointment</u>                 | <u>0.25</u>         |
|                                                        | <u>Desoximetasone</u>                       | <u>Gel</u>                             | <u>0.05</u>         |
|                                                        | <u>Diflorasone diacetate</u>                | <u>Cream</u>                           | <u>0.05</u>         |
|                                                        | <u>Fluocinonide</u>                         | <u>Cream, gel, ointment, solution</u>  | <u>0.05</u>         |
|                                                        | <u>Halcinonide</u>                          | <u>Cream, ointment</u>                 | <u>0.1</u>          |

|                             |                                   |                                                                                                                                                                                                                                                 |                     |
|-----------------------------|-----------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
|                             | <u>Mometasone furoate</u>         | <u>Ointment</u>                                                                                                                                                                                                                                 | <u>0.1</u>          |
|                             | <u>Triamcinolone acetonide</u>    | <u>Cream, ointment</u>                                                                                                                                                                                                                          | <u>0.5</u>          |
| <u>Medium potency</u>       | <u>Betamethasone valerate</u>     | <u>Cream, foam, lotion, ointment</u>                                                                                                                                                                                                            | <u>0.1</u>          |
|                             | <u>Clocortolone pivalate</u>      | <u>Cream</u>                                                                                                                                                                                                                                    | <u>0.1</u>          |
|                             | <u>Desoximetasone</u>             | <u>Cream</u>                                                                                                                                                                                                                                    | <u>0.05</u>         |
|                             | <u>Fluocinolone acetonide</u>     | <u>Cream, ointment</u>                                                                                                                                                                                                                          | <u>0.025</u>        |
|                             | <u>Flurandrenolide</u>            | <u>Cream, ointment, lotion</u>                                                                                                                                                                                                                  | <u>0.05</u>         |
|                             | <u>Fluticasone propionate</u>     | <u>Cream</u>                                                                                                                                                                                                                                    | <u>0.05</u>         |
|                             | <u>Fluticasone propionate</u>     | <u>Ointment</u>                                                                                                                                                                                                                                 | <u>0.005</u>        |
|                             | <u>Mometasone furoate</u>         | <u>Cream, lotion</u>                                                                                                                                                                                                                            | <u>0.1</u>          |
|                             | <u>Triamcinolone acetonide</u>    | <u>Cream, ointment, lotion</u>                                                                                                                                                                                                                  | <u>0.1</u>          |
| <u>Lower-medium potency</u> | <u>Hydrocortisone butyrate</u>    | <u>Cream, ointment, solution</u>                                                                                                                                                                                                                | <u>0.1</u>          |
|                             | <u>Hydrocortisone probutate</u>   | <u>Cream</u>                                                                                                                                                                                                                                    | <u>0.1</u>          |
|                             | <u>Hydrocortisone valerate</u>    | <u>Cream, ointment</u>                                                                                                                                                                                                                          | <u>0.2</u>          |
|                             | <u>Prednicarbate</u>              | <u>Cream</u>                                                                                                                                                                                                                                    | <u>0.1</u>          |
| <u>Low potency</u>          | <u>Alclometasone dipropionate</u> | <u>Cream, ointment</u>                                                                                                                                                                                                                          | <u>0.05</u>         |
|                             | <u>Desonide</u>                   | <u>Cream, gel, foam, ointment</u>                                                                                                                                                                                                               | <u>0.05</u>         |
|                             | <u>Fluocinolone acetonide</u>     | <u>Cream, solution</u>                                                                                                                                                                                                                          | <u>0.01</u>         |
| <u>Lowest potency</u>       | <u>Dexamethasone</u>              | <u>Cream</u>                                                                                                                                                                                                                                    | <u>0.1</u>          |
|                             | <u>Hydrocortisone</u>             | <u>Cream, lotion, ointment, solution</u>                                                                                                                                                                                                        | <u>0.25, 0.5, 1</u> |
|                             | <u>Hydrocortisone acetate</u>     | <u>Cream, ointment</u>                                                                                                                                                                                                                          | <u>0.5-1</u>        |
| <b>Table 2: PDL links</b>   |                                   |                                                                                                                                                                                                                                                 |                     |
| <b>Colorado</b>             |                                   | <a href="https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html</a> |                     |

|                              |                                                                                                                                                                                                                                                                               |
|------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Hawaii</b>                | <a href="https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html</a>                                   |
| <b>Maryland</b>              | <a href="https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-cp-pharmacy.html</a>                               |
| <b>New Jersey</b>            | <a href="https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html</a>                           |
| <b>New York</b>              | <a href="https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html</a>                               |
| <b>Rhode Island</b>          | <a href="https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html</a>                       |
| <b>Pennsylvania<br/>CHIP</b> | <a href="https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP">https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP</a> |
| <b>New Mexico</b>            | <a href="https://www.uhcprovider.com/en/health-plans-by-state/new-mexico-health-plans/nm-comm-plan-home/nm-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/new-mexico-health-plans/nm-comm-plan-home/nm-cp-pharmacy.html</a>                           |

### 3 . Revision History

| Date      | Notes                                    |
|-----------|------------------------------------------|
| 8/15/2025 | Added criteria for Giant Cell Arteritis. |

Rivfloza



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-373188                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Guideline Name</b> | Rivfloza                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Pennsylvania (ACUPA)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 9/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                        |                       |
|------------------------|-----------------------|
| Product Name: Rivfloza |                       |
| Approval Length        | 12 month(s)           |
| Therapy Stage          | Initial Authorization |

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Prior Authorization |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1 - ALL of the following:</b></p> <p><b>1.1</b> Patient has been established on therapy with Rivfloza under an active UnitedHealthcare medical benefit prior authorization for the treatment of primary hyperoxaluria type 1 (PH1)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>1.2</b> Submission of medical records (e.g., chart notes, laboratory values) documenting a positive clinical response to therapy from pre-treatment baseline (e.g., decreased urinary oxalate concentrations, decreased urinary oxalate: creatinine ratio, decreased plasma oxalate concentrations)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>1.3</b> Patient has NOT received a liver transplant</p> <p style="text-align: center;"><b>AND</b></p> <p><b>1.4</b> Patient has relatively preserved kidney function (e.g., eGFR [estimated glomerular filtration rate] greater than or equal to 30 mL/min/1.73 m<sup>2</sup>)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>1.5</b> Patient is NOT receiving Rivfloza in combination with Oxlumo (lumasiran)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>1.6</b> Prescribed by, or in consultation with, a specialist (e.g., geneticist, nephrologist, urologist) with expertise in the treatment of PH1</p> |                     |

**OR**

**2** - ALL of the following:

**2.1** Diagnosis of primary hyperoxaluria type 1 (PH1)

**AND**

**2.2** Confirmation of diagnosis based on BOTH of the following:

**2.2.1** Metabolic testing demonstrating ONE of the following:

**2.2.1.1** Increased urinary oxalate excretion (e.g., greater than 1 mmol/1.73 m<sup>2</sup> per day [90 mg/1.73 m<sup>2</sup> per day], increased urinary oxalate: creatinine ratio relative to normative values for age)

**OR**

**2.2.1.2** Increased plasma oxalate and glyoxylate concentrations

**AND**

**2.2.2** Genetic testing has confirmed a mutation in the alanine: glyoxylate aminotransferase (AGT or AGXT) gene

**AND**

**2.3** Patient has NOT received a liver transplant

**AND**

**2.4** Patient is at least 2 years of age or older

**AND**

**2.5** Patient has relatively preserved kidney function (e.g., eGFR [estimated glomerular filtration rate] greater than or equal to 30 mL/min/1.73 m<sup>2</sup>)

**AND**

**2.6** Patient is NOT receiving Rivfloza in combination with Oxlumio (lumasiran)

**AND**

**2.7** Prescribed by, or in consultation with, a specialist (e.g., geneticist, nephrologist, urologist) with expertise in the treatment of PH1

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                     |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name: Rivfloza                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                     |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 12 month(s)         |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Submission of medical records (e.g., chart notes, laboratory values) documenting a positive clinical response to therapy from pre-treatment baseline (e.g., decreased urinary oxalate concentrations, decreased urinary oxalate: creatinine ratio, decreased plasma oxalate concentrations)</p> <p><b>AND</b></p> <p><b>2</b> - Patient has NOT received a liver transplant</p> <p><b>AND</b></p> <p><b>3</b> - Patient has relatively preserved kidney function (e.g., eGFR [estimated glomerular filtration rate] greater than or equal to 30 mL/min/1.73 m<sup>2</sup>)</p> |                     |



**AND**

**4** - Patient is NOT receiving Rivfloza in combination with Oxlumio (lumasiran)

**AND**

**5** - Prescribed by, or in consultation with, a specialist (e.g., geneticist, nephrologist, urologist) with expertise in the treatment of PH1

## 2 . Revision History

| Date      | Notes                         |
|-----------|-------------------------------|
| 8/19/2025 | Updated formularies to add IN |

Romvimza



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-267198                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Guideline Name</b> | Romvimza                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 7/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                        |                                      |
|------------------------|--------------------------------------|
| Product Name: Romvimza |                                      |
| Diagnosis              | Tenosynovial Giant Cell Tumor (TGCT) |
| Approval Length        | 12 month(s)                          |
| Therapy Stage          | Initial Authorization                |

|                                                                                                                                                                                                                                                            |                     |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Guideline Type                                                                                                                                                                                                                                             | Prior Authorization |
| <b>Approval Criteria</b><br><br><b>1 - Diagnosis of tenosynovial giant cell tumor (TGCT)</b><br><br><p style="text-align: center;"><b>AND</b></p> <b>2 - Surgical resection will potentially cause worsening functional limitation or severe morbidity</b> |                     |

|                                                                                                                            |                                      |
|----------------------------------------------------------------------------------------------------------------------------|--------------------------------------|
| Product Name: Romvimza                                                                                                     |                                      |
| Diagnosis                                                                                                                  | Tenosynovial Giant Cell Tumor (TGCT) |
| Approval Length                                                                                                            | 12 month(s)                          |
| Therapy Stage                                                                                                              | Reauthorization                      |
| Guideline Type                                                                                                             | Prior Authorization                  |
| <b>Approval Criteria</b><br><br><b>1 - Patient does not show evidence of progressive disease while on Romvimza therapy</b> |                                      |

|                                                                                                                                                |                           |
|------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name: Romvimza                                                                                                                         |                           |
| Diagnosis                                                                                                                                      | NCCN Recommended Regimens |
| Approval Length                                                                                                                                | 12 month(s)               |
| Therapy Stage                                                                                                                                  | Initial Authorization     |
| Guideline Type                                                                                                                                 | Prior Authorization       |
| <b>Approval Criteria</b><br><br><b>1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium</b> |                           |

|                                                                                                     |                           |
|-----------------------------------------------------------------------------------------------------|---------------------------|
| Product Name: Romvimza                                                                              |                           |
| Diagnosis                                                                                           | NCCN Recommended Regimens |
| Approval Length                                                                                     | 12 month(s)               |
| Therapy Stage                                                                                       | Reauthorization           |
| Guideline Type                                                                                      | Prior Authorization       |
| <b>Approval Criteria</b><br><br>1 - Documentation of positive clinical response to Romvimza therapy |                           |

## 2 . Revision History

| Date      | Notes                         |
|-----------|-------------------------------|
| 5/14/2025 | Updated formularies to add IN |

Rozlytrek



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-183188                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Guideline Name</b> | Rozlytrek                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 4/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                        |                                    |
|------------------------|------------------------------------|
| Product Name:Rozlytrek |                                    |
| Diagnosis              | Non-Small Cell Lung Cancer (NSCLC) |
| Approval Length        | 12 month(s)                        |
| Therapy Stage          | Initial Authorization              |

|                                                                                                                                                                                                              |                     |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Guideline Type                                                                                                                                                                                               | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of metastatic non-small cell lung cancer (NSCLC)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Disease is ROS1 (gene)-positive</p> |                     |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                       |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Rozlytrek                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                       |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Solid Tumors          |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Presence of solid tumors [e.g., sarcoma, non-small cell lung cancer (NSCLC), salivary, breast, thyroid, colorectal, neuroendocrine, pancreatic, gynecological, cholangiocarcinoma, etc.]</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Disease is positive for neurotrophic receptor tyrosine kinase (NTRK) gene fusion [e.g., ETV6-NTRK3, TPM3-NTRK1, LMNA-NTRK1, etc.]</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Disease is without a known acquired resistance mutation [e.g., TRKA G595R substitution, TRKA G667C substitution, or other recurrent kinase domain (solvent front and xDFG) mutations]</p> |                       |

**AND**

**4** - Disease is ONE of the following:

- Metastatic
- Unresectable

**Product Name:**Rozlytrek

|                 |                                                  |
|-----------------|--------------------------------------------------|
| Diagnosis       | Non-Small Cell Lung Cancer (NSCLC), Solid Tumors |
| Approval Length | 12 month(s)                                      |
| Therapy Stage   | Reauthorization                                  |
| Guideline Type  | Prior Authorization                              |

**Approval Criteria**

**1** - Patient does not show evidence of progressive disease while on Rozlytrek therapy

**Product Name:**Rozlytrek

|                 |                           |
|-----------------|---------------------------|
| Diagnosis       | NCCN Recommended Regimens |
| Approval Length | 12 month(s)               |
| Therapy Stage   | Initial Authorization     |
| Guideline Type  | Prior Authorization       |

**Approval Criteria**

**1** - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

**Product Name:**Rozlytrek

|           |                           |
|-----------|---------------------------|
| Diagnosis | NCCN Recommended Regimens |
|-----------|---------------------------|

|                                                                                                      |                     |
|------------------------------------------------------------------------------------------------------|---------------------|
| Approval Length                                                                                      | 12 month(s)         |
| Therapy Stage                                                                                        | Reauthorization     |
| Guideline Type                                                                                       | Prior Authorization |
| <b>Approval Criteria</b><br><br>1 - Documentation of positive clinical response to Rozlytrek therapy |                     |

## 2 . Revision History

| Date      | Notes                                                                                                                                                      |
|-----------|------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 2/20/2025 | Combined formularies. Minor update to dx check criterion in NSCLC i<br>nitial auth section, with no changes to clinical intent. Minor cosmetic<br>updates. |



Rubraca



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-257188                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Guideline Name</b> | Rubraca                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Washington (ACUWA, ACUWAAHE, ACUWAC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 7/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                      |                                                                             |
|----------------------|-----------------------------------------------------------------------------|
| Product Name:Rubraca |                                                                             |
| Diagnosis            | Epithelial ovarian cancer, fallopian tube cancer, primary peritoneal cancer |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                       |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of ONE of the following:</p> <ul style="list-style-type: none"> <li>• Epithelial ovarian cancer</li> <li>• Fallopian tube cancer</li> <li>• Primary peritoneal cancer</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p>2 - BOTH of the following:</p> <p>2.1 Cancer has a deleterious BRCA mutation</p> <p style="text-align: center;"><b>AND</b></p> <p>2.2 To be used as maintenance therapy in individuals who are in complete or partial response to platinum-based chemotherapy</p> |                       |

|                                                                                                          |                       |
|----------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name: Rubraca                                                                                    |                       |
| Diagnosis                                                                                                | Prostate cancer       |
| Approval Length                                                                                          | 12 month(s)           |
| Therapy Stage                                                                                            | Initial Authorization |
| Guideline Type                                                                                           | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of metastatic, castration-resistant prostate cancer</p> |                       |

**AND**

**2** - Cancer has a deleterious BRCA mutation

**AND**

**3** - ONE of the following:

**3.1** Failure to androgen receptor-directed therapy [e.g., Zytiga (abiraterone), Xtandi (enzalutamide), Erleada (apalutamide)] as confirmed by claims history or submission of medical records

**OR**

**3.2** Contraindication or intolerance to androgen receptor-directed therapy [e.g., Zytiga (abiraterone), Xtandi (enzalutamide), Erleada (apalutamide)] (please specify intolerance or contraindication)

**AND**

**4** - ONE of the following:

**4.1** Used in combination with a gonadotropin-releasing hormone (GnRH) analog [e.g., Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix)]

**OR**

**4.2** Patient has had bilateral orchiectomy

|                       |                       |
|-----------------------|-----------------------|
| Product Name: Rubraca |                       |
| Diagnosis             | Uterine cancer        |
| Approval Length       | 12 month(s)           |
| Therapy Stage         | Initial Authorization |
| Guideline Type        | Prior Authorization   |

**Approval Criteria**

**1** - Diagnosis of BRCA altered uterine leiomyosarcoma (uLMS)

**AND**

**2** - Disease has progressed following prior treatment with ONE of the following:

- Gemcitabine plus docetaxel
- Doxorubicin

|                                                                                                                                                                                                                                                                                                                      |                       |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name: Rubraca                                                                                                                                                                                                                                                                                                |                       |
| Diagnosis                                                                                                                                                                                                                                                                                                            | Pancreatic cancer     |
| Approval Length                                                                                                                                                                                                                                                                                                      | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                        | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                       | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of pancreatic adenocarcinoma</p> <p><b>AND</b></p> <p><b>2</b> - Disease is metastatic</p> <p><b>AND</b></p> <p><b>3</b> - Presence of ONE of the following:</p> <p><b>3.1</b> Deleterious or suspected deleterious germline or somatic BRCA1/2 mutation</p> |                       |

**OR**

**3.2** Deleterious or suspected deleterious germline or somatic PALB2 mutation

**AND**

**4** - Disease has NOT progressed while receiving at least 16 weeks of a first-line platinum-based chemotherapy regimen

| Product Name: Rubraca                                                                                                 |                                                                                                                                 |
|-----------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------|
| Diagnosis                                                                                                             | Epithelial ovarian cancer, fallopian tube cancer, primary peritoneal cancer, Prostate cancer, Uterine cancer, Pancreatic cancer |
| Approval Length                                                                                                       | 12 month(s)                                                                                                                     |
| Therapy Stage                                                                                                         | Reauthorization                                                                                                                 |
| Guideline Type                                                                                                        | Prior Authorization                                                                                                             |
| <b>Approval Criteria</b><br><b>1</b> - Patient does NOT show evidence of progressive disease while on Rubraca therapy |                                                                                                                                 |

| Product Name: Rubraca                                                                                                                   |                           |
|-----------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Diagnosis                                                                                                                               | NCCN Recommended Regimens |
| Approval Length                                                                                                                         | 12 month(s)               |
| Therapy Stage                                                                                                                           | Initial Authorization     |
| Guideline Type                                                                                                                          | Prior Authorization       |
| <b>Approval Criteria</b><br><b>1</b> - Use supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium |                           |

|                                                                                                    |                           |
|----------------------------------------------------------------------------------------------------|---------------------------|
| Product Name: Rubraca                                                                              |                           |
| Diagnosis                                                                                          | NCCN Recommended Regimens |
| Approval Length                                                                                    | 12 month(s)               |
| Therapy Stage                                                                                      | Reauthorization           |
| Guideline Type                                                                                     | Prior Authorization       |
| <b>Approval Criteria</b><br><br>1 - Documentation of positive clinical response to Rubraca therapy |                           |

## 2 . Revision History

| Date     | Notes                                                                                      |
|----------|--------------------------------------------------------------------------------------------|
| 5/5/2025 | Updated formularies. Removed requirement for taxane-based chemotherapy for prostate cancer |

Ruconest



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-268187                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Guideline Name</b> | Ruconest                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 7/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                       |                             |
|-----------------------|-----------------------------|
| Product Name:Ruconest |                             |
| Diagnosis             | Hereditary Angioedema (HAE) |
| Approval Length       | 12 month(s)                 |
| Therapy Stage         | Initial Authorization       |
| Guideline Type        | Prior Authorization         |

## **Approval Criteria**

**1** - Diagnosis of hereditary angioedema (HAE) as confirmed by ONE of the following:

**1.1** C1 inhibitor (C1-INH) deficiency or dysfunction (Type I or II HAE) as documented by ONE of the following (per laboratory standard):

- C1-INH antigenic level below the lower limit of normal
- C1-INH functional level below the lower limit of normal

**OR**

**1.2** HAE with normal C1 inhibitor levels and ONE of the following:

- Confirmed presence of variant(s) in the gene(s) for factor XII, angiotensin-1, plasminogen-1, kininogen-1, myoferlin, or heparan sulfate-glucosamine 3-O-sulfotransferase 6
- Recurring angioedema attacks that are refractory to high-dose antihistamines with confirmed family history of angioedema
- Recurring angioedema attacks that are refractory to high-dose antihistamines with unknown background de-novo mutation(s) (i.e., no family history) (HAE-unknown)

**AND**

**2** - Prescribed for the acute treatment of HAE attacks

**AND**

**3** - Not used in combination with other products indicated for the acute treatment of HAE attacks (e.g., Berinert, Firazyr)

**AND**

**4** - Prescribed by ONE of the following:

- Immunologist
- Allergist



|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                             |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|
| Product Name: Ruconest                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                             |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Hereditary Angioedema (HAE) |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 12 month(s)                 |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Reauthorization             |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Prior Authorization         |
| <p><b>Approval Criteria</b></p> <p>1 - Documentation of positive clinical response to Ruconest therapy</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Prescribed for the acute treatment of HAE attacks</p> <p style="text-align: center;"><b>AND</b></p> <p>3 - Not used in combination with other products indicated for the acute treatment of HAE attacks (e.g., Berinert, Firazyr)</p> <p style="text-align: center;"><b>AND</b></p> <p>4 - Prescribed by ONE of the following:</p> <ul style="list-style-type: none"> <li>• Immunologist</li> <li>• Allergist</li> </ul> |                             |

## 2 . Revision History

| Date      | Notes                                                  |
|-----------|--------------------------------------------------------|
| 5/14/2025 | Combined formularies. No changes to clinical criteria. |

Rydapt



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-370209                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Guideline Name</b> | Rydapt                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Washington (ACUWA, ACUWAAHE, ACUWAC)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 9/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                     |                              |
|---------------------|------------------------------|
| Product Name:Rydapt |                              |
| Diagnosis           | Acute Myeloid Leukemia (AML) |
| Approval Length     | 12 month(s)                  |

|                                                                                                                                                                                                                                                                                                                           |                       |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                                                                                                                                                                                                                                                             | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                            | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of acute myeloid leukemia (AML)</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - AML is FLT3 mutation-positive</p> <p style="text-align: center;"><b>AND</b></p> <p>3 - Rydapt will be used in combination with standard induction and consolidation therapy</p> |                       |

|                                                                                                                                                                                                                                                                                       |                       |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Rydapt                                                                                                                                                                                                                                                                   |                       |
| Diagnosis                                                                                                                                                                                                                                                                             | Systemic Mastocytosis |
| Approval Length                                                                                                                                                                                                                                                                       | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                         | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                        | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of ONE of the following:</p> <ul style="list-style-type: none"> <li>Aggressive systemic mastocytosis (ASM)</li> <li>Systemic mastocytosis with associated hematologic neoplasm (SM-AHN)</li> <li>Mast cell leukemia (MCL)</li> </ul> |                       |

|                     |                            |
|---------------------|----------------------------|
| Product Name:Rydapt |                            |
| Diagnosis           | Myeloid/Lymphoid Neoplasms |
| Approval Length     | 12 month(s)                |

|                                                                                                                                                                                                                                                                                                                                            |                       |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                                                                                                                                                                                                                                                                              | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                             | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of lymphoid, myeloid, or mixed lineage neoplasms with eosinophilia</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - ONE of the following:</p> <ul style="list-style-type: none"> <li>• Presence of an FGFR1 rearrangement</li> <li>• Presence of an FLT3 rearrangement</li> </ul> |                       |

|                                                                                                                          |                                                                                 |
|--------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------|
| Product Name:Rydapt                                                                                                      |                                                                                 |
| Diagnosis                                                                                                                | Acute Myeloid Leukemia (AML), Systemic Mastocytosis, Myeloid/Lymphoid Neoplasms |
| Approval Length                                                                                                          | 12 month(s)                                                                     |
| Therapy Stage                                                                                                            | Reauthorization                                                                 |
| Guideline Type                                                                                                           | Prior Authorization                                                             |
| <p><b>Approval Criteria</b></p> <p>1 - Patient does not show evidence of progressive disease while on Rydapt therapy</p> |                                                                                 |

|                     |                           |
|---------------------|---------------------------|
| Product Name:Rydapt |                           |
| Diagnosis           | NCCN Recommended Regimens |
| Approval Length     | 12 month(s)               |
| Therapy Stage       | Initial Authorization     |
| Guideline Type      | Prior Authorization       |

**Approval Criteria**

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

|                                                                                                          |                           |
|----------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Rydapt                                                                                      |                           |
| Diagnosis                                                                                                | NCCN Recommended Regimens |
| Approval Length                                                                                          | 12 month(s)               |
| Therapy Stage                                                                                            | Reauthorization           |
| Guideline Type                                                                                           | Prior Authorization       |
| <p><b>Approval Criteria</b></p> <p>1 - Documentation of positive clinical response to Rydapt therapy</p> |                           |

## 2 . Revision History

| Date      | Notes                                                                              |
|-----------|------------------------------------------------------------------------------------|
| 8/15/2025 | Combined formularies. Minor wording update to Myeloid/Lymphoid Neoplasms criteria. |

Sandostatin



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|-----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-242247                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Guideline Name</b> | Sandostatin                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania (ACUPA)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Washington (ACUWA, ACUWAAHE, ACUWAC)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 7/1/2025 |
|-----------------|----------|

## 1 . Criteria

Product Name: Brand Sandostatin, generic octreotide

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                       |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Acromegaly            |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of acromegaly</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - ONE of the following:</p> <p>2.1 Inadequate response to ONE of the following:</p> <ul style="list-style-type: none"> <li>• Surgical resection</li> <li>• Pituitary irradiation</li> <li>• Dopamine agonist (e.g., bromocriptine, cabergoline) therapy</li> </ul> <p style="text-align: center;"><b>OR</b></p> <p>2.2 NOT a candidate for any of the following:</p> <ul style="list-style-type: none"> <li>• Surgical resection</li> <li>• Pituitary irradiation</li> <li>• Dopamine agonist (e.g., bromocriptine, cabergoline) therapy</li> </ul> |                       |

|                                                     |                       |
|-----------------------------------------------------|-----------------------|
| Product Name: Brand Sandostatin, generic octreotide |                       |
| Diagnosis                                           | Meningioma            |
| Approval Length                                     | 12 month(s)           |
| Therapy Stage                                       | Initial Authorization |
| Guideline Type                                      | Prior Authorization   |
|                                                     |                       |

**Approval Criteria**

1 - Diagnosis of meningioma

**AND**

2 - Disease is surgically inaccessible

**AND**

3 - ONE of the following:

- Disease is recurrent
- Disease is progressive

**AND**

4 - Radiation is not possible

Product Name: Brand Sandostatin, generic octreotide

|           |                                   |
|-----------|-----------------------------------|
| Diagnosis | Neuroendocrine and Adrenal Tumors |
|-----------|-----------------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

1 - Patient has a neuroendocrine tumor [i.e., carcinoid tumors, Islet cell tumors, gastrinomas, glucagonomas, insulinomas, lung tumors, somatostatinomas, tumors of the pancreas, GI (gastrointestinal) tract, lung and thymus, adrenal glands, and vasoactive intestinal polypeptidomas (VIPomas)]

**OR**

2 - BOTH of the following:



**2.1 ONE of the following:**

- Diagnosis of Pheochromocytoma or Paraganglioma
- Well-differentiated grade 3 neuroendocrine tumor

**AND**

**2.2 Disease is ONE of the following:**

- Locally unresectable
- Metastatic

|                                                                                                                                                                                                                                                                                         |                                   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|
| Product Name:Brand Sandostatin, generic octreotide                                                                                                                                                                                                                                      |                                   |
| Diagnosis                                                                                                                                                                                                                                                                               | Neuroendocrine and Adrenal Tumors |
| Approval Length                                                                                                                                                                                                                                                                         | 12 month(s)                       |
| Therapy Stage                                                                                                                                                                                                                                                                           | Reauthorization                   |
| Guideline Type                                                                                                                                                                                                                                                                          | Prior Authorization               |
| <p><b>Approval Criteria</b></p> <p>1 - Patient does not show evidence of progressive disease while on the requested therapy</p> <p><b>OR</b></p> <p>2 - Documentation of positive clinical response (e.g., suppression of severe diarrhea, flushing, etc.) to the requested therapy</p> |                                   |

|                                                    |                             |
|----------------------------------------------------|-----------------------------|
| Product Name:Brand Sandostatin, generic octreotide |                             |
| Diagnosis                                          | Thymoma or Thymic Carcinoma |
| Approval Length                                    | 12 month(s)                 |
| Therapy Stage                                      | Initial Authorization       |
| Guideline Type                                     | Prior Authorization         |

## Approval Criteria

1 - Diagnosis of thymoma or thymic carcinoma

**AND**

2 - ONE of the following:

2.1 Used as a second-line therapy for ONE of the following:

- Unresectable locally advanced disease
- Solitary metastasis or ipsilateral pleural metastasis
- Extrathoracic metastatic disease

**OR**

2.2 BOTH of the following:

2.2.1 Used as first line therapy for ONE of the following:

- Potentially resectable locally advanced disease
- Potentially resectable solitary metastasis or ipsilateral pleural metastasis
- Consideration following surgery for solitary metastasis or ipsilateral pleural metastasis
- Medically inoperable/unresectable solitary metastasis or ipsilateral pleural metastasis
- Extrathoracic metastatic disease
- Postoperative treatment for thymoma after R2 resection
- Preoperative systemic therapy for surgically resectable disease if R0 resection uncertain

**AND**

2.2.2 Patient is unable to tolerate first-line combination regimens

|                                                     |                                         |
|-----------------------------------------------------|-----------------------------------------|
| Product Name: Brand Sandostatin, generic octreotide |                                         |
| Diagnosis                                           | Meningioma, Thymoma or Thymic Carcinoma |
| Approval Length                                     | 12 month(s)                             |
| Therapy Stage                                       | Reauthorization                         |

|                                                                                                                             |                     |
|-----------------------------------------------------------------------------------------------------------------------------|---------------------|
| Guideline Type                                                                                                              | Prior Authorization |
| <b>Approval Criteria</b><br><b>1</b> - Patient does not show evidence of progressive disease while on the requested therapy |                     |

|                                                                                                                                                                                   |                             |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|
| Product Name:Brand Sandostatin, generic octreotide                                                                                                                                |                             |
| Diagnosis                                                                                                                                                                         | Malignant Bowel Obstruction |
| Approval Length                                                                                                                                                                   | 12 month(s)                 |
| Therapy Stage                                                                                                                                                                     | Initial Authorization       |
| Guideline Type                                                                                                                                                                    | Prior Authorization         |
| <b>Approval Criteria</b><br><b>1</b> - Diagnosis of malignant bowel obstruction<br><br><p style="text-align: center;"><b>AND</b></p> <b>2</b> - Gut function cannot be maintained |                             |

|                                                                                                                     |                                                 |
|---------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|
| Product Name:Brand Sandostatin, generic octreotide                                                                  |                                                 |
| Diagnosis                                                                                                           | Chemotherapy- and/or Radiation-Induced Diarrhea |
| Approval Length                                                                                                     | 12 month(s)                                     |
| Therapy Stage                                                                                                       | Initial Authorization                           |
| Guideline Type                                                                                                      | Prior Authorization                             |
| <b>Approval Criteria</b><br><b>1</b> - Diagnosis of diarrhea due to concurrent cancer chemotherapy and/or radiation |                                                 |

**AND**

**2** - ONE of the following:

**2.1** Presence of Grade 3 or 4 severe diarrhea

**OR**

**2.2** Patient is in palliative or end of life care

|                                                                                                                     |                                   |
|---------------------------------------------------------------------------------------------------------------------|-----------------------------------|
| Product Name: Brand Sandostatin, generic octreotide                                                                 |                                   |
| Diagnosis                                                                                                           | Bleeding Gastroesophageal Varices |
| Approval Length                                                                                                     | 12 month(s)                       |
| Therapy Stage                                                                                                       | Initial Authorization             |
| Guideline Type                                                                                                      | Prior Authorization               |
| <b>Approval Criteria</b><br><b>1</b> - Diagnosis of bleeding gastroesophageal varices associated with liver disease |                                   |

|                                                                                                                                            |                           |
|--------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name: Brand Sandostatin, generic octreotide                                                                                        |                           |
| Diagnosis                                                                                                                                  | NCCN Recommended Regimens |
| Approval Length                                                                                                                            | 12 month(s)               |
| Therapy Stage                                                                                                                              | Initial Authorization     |
| Guideline Type                                                                                                                             | Prior Authorization       |
| <b>Approval Criteria</b><br><b>1</b> - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium |                           |

|                                                                                                          |                                                                                                                                                        |
|----------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|
| Product Name:Brand Sandostatin, generic octreotide                                                       |                                                                                                                                                        |
| Diagnosis                                                                                                | Acromegaly, Malignant Bowel Obstruction, Chemotherapy- and/or Radiation-Induced Diarrhea, Bleeding Gastroesophageal Varices, NCCN Recommended Regimens |
| Approval Length                                                                                          | 12 month(s)                                                                                                                                            |
| Therapy Stage                                                                                            | Reauthorization                                                                                                                                        |
| Guideline Type                                                                                           | Prior Authorization                                                                                                                                    |
| <b>Approval Criteria</b><br><br>1 - Documentation of positive clinical response to the requested therapy |                                                                                                                                                        |

## 2 . Revision History

| Date      | Notes                                                                                                                                                                                                                                                                                                 |
|-----------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 4/22/2025 | Updated formularies. Updated wording within acromegaly and meningioma coverage criteria without change in clinical intent. Added criteria for well-differentiated grade 3 neuroendocrine tumor. Updated criteria for thymoma or thymic carcinoma. Removed HIV/AIDS-related diarrhea coverage criteria |

Savaysa



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-205208                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Guideline Name</b> | Savaysa                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 4/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                      |                                 |
|----------------------|---------------------------------|
| Product Name:Savaysa |                                 |
| Diagnosis            | Therapy upon hospital discharge |
| Approval Length      | 35 Day(s)                       |
| Guideline Type       | Prior Authorization             |

**Approval Criteria**

1 - Medication is being used as continuation of therapy upon hospital discharge

Product Name:Savaysa

|           |                                                                                               |
|-----------|-----------------------------------------------------------------------------------------------|
| Diagnosis | Stroke & Systemic Embolism Prevention in Adult Patients with Non-Valvular Atrial Fibrillation |
|-----------|-----------------------------------------------------------------------------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

1 - Diagnosis of atrial fibrillation (AF)

**AND**

2 - Patient does not have an artificial heart valve

**AND**

3 - One of the following:

3.1 Failure to Eliquis as confirmed by claims history or submission of medical records

**OR**

3.2 History of contraindication or intolerance to Eliquis (please specify contraindication or intolerance)

**OR**

3.3 Continuation of prior Savaysa therapy

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                        |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------|
| Product Name:Savaysa                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                        |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Deep Vein Thrombosis or Pulmonary Embolism Treatment in Adult Patients |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 12 month(s)                                                            |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Prior Authorization                                                    |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of one of the following:</p> <ul style="list-style-type: none"> <li>• Deep vein thrombosis (DVT)</li> <li>• Pulmonary embolism (PE)</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Patient does not have an artificial heart valve</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - One of the following:</p> <p><b>3.1</b> Failure to Eliquis as confirmed by claims history or submission of medical records</p> <p style="text-align: center;"><b>OR</b></p> <p><b>3.2</b> History of contraindication or intolerance to Eliquis (please specify contraindication or intolerance)</p> <p style="text-align: center;"><b>OR</b></p> <p><b>3.3</b> Continuation of prior Savaysa therapy</p> |                                                                        |

## 2 . Revision History



| Date      | Notes |
|-----------|-------|
| 2/28/2025 | New   |

Scemblix



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-164748                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Guideline Name</b> | Scemblix                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 3/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                       |                                |
|-----------------------|--------------------------------|
| Product Name:Scemblix |                                |
| Diagnosis             | Chronic Myeloid Leukemia (CML) |
| Approval Length       | 12 month(s)                    |
| Therapy Stage         | Initial Authorization          |

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Prior Authorization |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of chronic myeloid leukemia (CML)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Disease is Philadelphia chromosome (Ph+) or BCR::ABL1-positive</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - ONE of the following:</p> <ul style="list-style-type: none"> <li>• Used in newly diagnosed chronic phase CML (CP-CML)</li> <li>• Used in previously treated chronic phase CML (CP-CML)</li> <li>• Used in chronic phase CML (CP-CML) positive for a T315I mutation</li> <li>• Used in accelerated phase CML as primary treatment as a single agent</li> </ul> |                     |

| Product Name:Scemblix                                                                                                                                                                                                                  |                                                                          |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------|
| Diagnosis                                                                                                                                                                                                                              | Myeloid/Lymphoid Neoplasms with Eosinophilia and ABL1 Gene Rearrangement |
| Approval Length                                                                                                                                                                                                                        | 12 month(s)                                                              |
| Therapy Stage                                                                                                                                                                                                                          | Initial Authorization                                                    |
| Guideline Type                                                                                                                                                                                                                         | Prior Authorization                                                      |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of myeloid/lymphoid neoplasm with eosinophilia and ABL1 rearrangement</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Disease is in chronic or blast phase</p> |                                                                          |

|                                                                                                                            |                                                                                                          |
|----------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------|
| Product Name:Scemblix                                                                                                      |                                                                                                          |
| Diagnosis                                                                                                                  | Chronic Myeloid Leukemia (CML), Myeloid/Lymphoid Neoplasms with Eosinophilia and ABL1 Gene Rearrangement |
| Approval Length                                                                                                            | 12 month(s)                                                                                              |
| Therapy Stage                                                                                                              | Reauthorization                                                                                          |
| Guideline Type                                                                                                             | Prior Authorization                                                                                      |
| <b>Approval Criteria</b><br><br><b>1</b> - Patient does not show evidence of progressive disease while on Scemblix therapy |                                                                                                          |

|                                                                                                                                                |                           |
|------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Scemblix                                                                                                                          |                           |
| Diagnosis                                                                                                                                      | NCCN Recommended Regimens |
| Approval Length                                                                                                                                | 12 month(s)               |
| Therapy Stage                                                                                                                                  | Initial Authorization     |
| Guideline Type                                                                                                                                 | Prior Authorization       |
| <b>Approval Criteria</b><br><br><b>1</b> - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium |                           |

|                          |                           |
|--------------------------|---------------------------|
| Product Name:Scemblix    |                           |
| Diagnosis                | NCCN Recommended Regimens |
| Approval Length          | 12 month(s)               |
| Therapy Stage            | Reauthorization           |
| Guideline Type           | Prior Authorization       |
| <b>Approval Criteria</b> |                           |

1 - Documentation of positive clinical response to Scemblix therapy

## 2 . Revision History

| Date     | Notes                                                             |
|----------|-------------------------------------------------------------------|
| 2/5/2025 | Updated formularies. Updated GPIs. Updated initial auth criteria. |

Sensipar



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-267192                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Guideline Name</b> | Sensipar                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Arizona (ACUAZ, ACUAZEC)</li> <li>• Medicaid - Community &amp; State Michigan (ACUMI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Pennsylvania (ACUPA)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 7/1/2025 |
|-----------------|----------|

## 1 . Criteria

Product Name: Brand Sensipar, generic cinacalcet

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                       |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Prescribed by or in consultation with an oncologist, endocrinologist, or nephrologist</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - ONE of the following:</p> <p>2.1 BOTH of the following:</p> <ul style="list-style-type: none"> <li>• Diagnosis of secondary hyperparathyroidism with chronic kidney disease</li> <li>• Patient is on dialysis</li> </ul> <p style="text-align: center;"><b>OR</b></p> <p>2.2 Diagnosis of hypercalcemia with parathyroid carcinoma</p> <p style="text-align: center;"><b>OR</b></p> <p>2.3 ALL of the following:</p> <ul style="list-style-type: none"> <li>• Diagnosis of primary hyperparathyroidism (HPT)</li> <li>• Severe hypercalcemia [serum calcium level greater than 12.5 mg/dL (milligrams/deciliter)] due to primary HPT</li> <li>• Patient is unable to undergo parathyroidectomy</li> </ul> |                       |

|                                                  |                     |
|--------------------------------------------------|---------------------|
| Product Name: Brand Sensipar, generic cinacalcet |                     |
| Approval Length                                  | 12 month(s)         |
| Therapy Stage                                    | Reauthorization     |
| Guideline Type                                   | Prior Authorization |

**Approval Criteria**

1 - Patient has experienced a reduction in serum calcium from baseline

**2 . Revision History**

| Date      | Notes                                     |
|-----------|-------------------------------------------|
| 5/14/2025 | Updated formularies to add PA CAID and IN |



## SGLT2 Inhibitors



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-220212                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Guideline Name</b> | SGLT2 Inhibitors                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 5/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                                     |                     |
|-------------------------------------|---------------------|
| Product Name: Steglatro, Segluromet |                     |
| Approval Length                     | 12 month(s)         |
| Guideline Type                      | Prior Authorization |
| Approval Criteria                   |                     |

**1 - Submission of medical records (e.g., chart notes) confirming diagnosis of type 2 diabetes mellitus as evidenced by ONE of the following laboratory values**

- A1C greater than or equal to 6.5%
- Fasting plasma glucose (FPG) greater than or equal to 126 mg/dL
- 2-hour plasma glucose (PG) greater than or equal to 200 mg/dL during oral glucose tolerance test
- Random plasma glucose greater than or equal to 200 mg/dL in patient with classic symptoms of hyperglycemia or hyperglycemic crisis

**OR**

**2 - For patients requiring ongoing treatment for type 2 diabetes mellitus (i.e., diagnosed greater than 2 years ago), submission of medical records (e.g., chart notes) confirming diagnosis of type 2 diabetes mellitus**

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                       |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name: Jardiance                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                       |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1 - For diagnosis of type 2 diabetes mellitus, BOTH of the following:</b></p> <p><b>1.1 ONE of the following:</b></p> <p><b>1.1.1 Submission of medical records (e.g., chart notes) confirming diagnosis of type 2 diabetes mellitus as evidenced by one of the following laboratory values</b></p> <ul style="list-style-type: none"> <li>• A1C greater than or equal to 6.5%</li> <li>• Fasting plasma glucose (FPG) greater than or equal to 126 mg/dL</li> <li>• 2-hour plasma glucose (PG) greater than or equal to 200 mg/dL during oral glucose tolerance test</li> <li>• Random plasma glucose greater than or equal to 200 mg/dL in patient with classic symptoms of hyperglycemia or hyperglycemic crisis</li> </ul> <p style="text-align: center;"><b>OR</b></p> |                       |

**1.1.2** For patients requiring ongoing treatment for type 2 diabetes mellitus (i.e., diagnosed greater than 2 years ago), submission of medical records (e.g., chart notes) confirming diagnosis of type 2 diabetes mellitus

**AND**

**1.2** ONE of the following:

**1.2.1** Failure to ONE of the following therapies for 90 days confirmed by claims history or submission of medical records:

- Steglatro (ertugliflozin) OR Segluromet (ertugliflozin/metformin)
- Dapagliflozin (Farxiga authorized generic)

**OR**

**1.2.2** History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- Steglatro (ertugliflozin) OR Segluromet (ertugliflozin/metformin)
- Dapagliflozin (Farxiga authorized generic)

**OR**

**2** - For diagnosis of heart failure (NYHA class II-IV), ONE of the following:

- Failure to dapagliflozin (Farxiga authorized generic) as confirmed by claims history or submission of medical records
- History of intolerance or contraindication to dapagliflozin (Farxiga authorized generic) (please specify intolerance or contraindication)

**OR**

**3** - For diagnosis of chronic kidney disease (CKD), BOTH of the following:

**3.1** ONE of the following:

- Patient is currently taking an ACE inhibitor or ARB, confirmed by claims history or submission of medical records

- History of intolerance or contraindication to ACE inhibitor or ARB (please specify intolerance or contraindication)

**AND**

**3.2 ONE of the following:**

- Failure to dapagliflozin (Farxiga authorized generic) as confirmed by claims history or submission of medical records
- History of intolerance or contraindication to dapagliflozin (Farxiga authorized generic) (please specify intolerance or contraindication)

|                                                                                                   |                     |
|---------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Jardiance                                                                            |                     |
| Approval Length                                                                                   | 12 month(s)         |
| Therapy Stage                                                                                     | Reauthorization     |
| Guideline Type                                                                                    | Prior Authorization |
| <b>Approval Criteria</b><br><br><b>1 - Documentation of positive clinical response to therapy</b> |                     |

|                                                                                                                                                                                                                                                                                                                                    |                       |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Invokana                                                                                                                                                                                                                                                                                                              |                       |
| Approval Length                                                                                                                                                                                                                                                                                                                    | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                      | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                     | Prior Authorization   |
| <b>Approval Criteria</b><br><br><b>1 - ONE of the following:</b><br><br><b>1.1 Submission of medical records (e.g., chart notes) confirming diagnosis of type 2 diabetes mellitus as evidenced by ONE of the following laboratory values</b> <ul style="list-style-type: none"> <li>• A1C greater than or equal to 6.5%</li> </ul> |                       |

- Fasting plasma glucose (FPG) greater than or equal to 126 mg/dL
- 2-hour plasma glucose (PG) greater than or equal to 200 mg/dL during oral glucose tolerance test
- Random plasma glucose greater than or equal to 200 mg/dL in patient with classic symptoms of hyperglycemia or hyperglycemic crisis

**OR**

**1.2** For patients requiring ongoing treatment for type 2 diabetes mellitus (i.e., diagnosed greater than 2 years ago), submission of medical records (e.g., chart notes) confirming diagnosis of type 2 diabetes mellitus

**AND**

**2** - ONE of the following:

**2.1** ONE of the following:

**2.1.1** Failure to ONE of the following therapies for 90 days confirmed by claims history or submission of medical records:

- Steglatro (ertugliflozin) OR Segluromet (ertugliflozin/metformin)
- Dapagliflozin (Farxiga authorized generic)

**OR**

**2.1.2** History of contraindication or intolerance to BOTH of the following (please specify contraindication or intolerance):

- Steglatro (ertugliflozin) OR Segluromet (ertugliflozin/metformin)
- Dapagliflozin (Farxiga authorized generic)

**OR**

**2.2** Documented history of diabetic nephropathy with albuminuria

|                        |             |
|------------------------|-------------|
| Product Name: Invokana |             |
| Approval Length        | 12 month(s) |

|                                                                                                   |                     |
|---------------------------------------------------------------------------------------------------|---------------------|
| Therapy Stage                                                                                     | Reauthorization     |
| Guideline Type                                                                                    | Prior Authorization |
| <b>Approval Criteria</b><br><br><b>1</b> - Documentation of positive clinical response to therapy |                     |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                     |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Dapagliflozin (Farxiga authorized generic)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                     |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | 12 month(s)         |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Prior Authorization |
| <b>Approval Criteria</b><br><br><b>1</b> - For diagnosis of type 2 diabetes mellitus, ONE of the following:<br><br><b>1.1</b> Submission of medical records (e.g., chart notes) confirming diagnosis of type 2 diabetes mellitus as evidenced by ONE of the following laboratory values <ul style="list-style-type: none"> <li>• A1C greater than or equal to 6.5%</li> <li>• Fasting plasma glucose (FPG) greater than or equal to 126 mg/dL</li> <li>• 2-hour plasma glucose (PG) greater than or equal to 200 mg/dL during oral glucose tolerance test</li> <li>• Random plasma glucose greater than or equal to 200 mg/dL in patient with classic symptoms of hyperglycemia or hyperglycemic crisis</li> </ul> <p style="text-align: center;"><b>OR</b></p> <b>1.2</b> For patients requiring ongoing treatment for type 2 diabetes mellitus (i.e., diagnosed greater than 2 years ago), submission of medical records (e.g., chart notes) confirming diagnosis of type 2 diabetes mellitus <p style="text-align: center;"><b>OR</b></p> <b>2</b> - Diagnosis of heart failure (NYHA class II-IV) |                     |

**OR**

**3 - Diagnosis of chronic kidney disease**

Product Name:Farxiga

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

### Approval Criteria

**1 - ONE of the following:**

**1.1** For diagnosis of type 2 diabetes mellitus, ONE of the following:

**1.1.1** Submission of medical records (e.g., chart notes) confirming diagnosis of type 2 diabetes mellitus as evidenced by ONE of the following laboratory values

- A1C greater than or equal to 6.5%
- Fasting plasma glucose (FPG) greater than or equal to 126 mg/dL
- 2-hour plasma glucose (PG) greater than or equal to 200 mg/dL during oral glucose tolerance test
- Random plasma glucose greater than or equal to 200 mg/dL in patient with classic symptoms of hyperglycemia or hyperglycemic crisis

**OR**

**1.1.2** For patients requiring ongoing treatment for type 2 diabetes mellitus (i.e., diagnosed greater than 2 years ago), submission of medical records (e.g., chart notes) confirming diagnosis of type 2 diabetes mellitus

**OR**

**1.2** Diagnosis of heart failure (NYHA class II-IV)

**OR**

**1.3** Diagnosis of chronic kidney disease

**AND**

**2** - The prescriber has given a clinical reason or special circumstance why the patient is unable to use dapagliflozin (Farxiga authorized generic) (please document reason/special circumstance)

|                                                                                                                                                                                                                                                                                                                                           |                     |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Farxiga                                                                                                                                                                                                                                                                                                                      |                     |
| Approval Length                                                                                                                                                                                                                                                                                                                           | 12 month(s)         |
| Therapy Stage                                                                                                                                                                                                                                                                                                                             | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                                                                                                            | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of positive clinical response to therapy</p> <p><b>AND</b></p> <p><b>2</b> - The prescriber has given a clinical reason or special circumstance why the patient is unable to use dapagliflozin (Farxiga authorized generic) (please document reason/special circumstance)</p> |                     |

|                                                                                                                              |                       |
|------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Brenzavvy, Bexagliflozin, Synjardy, Synjardy XR, Invokamet, Invokamet XR, Xigduo XR, Dapagliflozin/Metformin ER |                       |
| Approval Length                                                                                                              | 12 month(s)           |
| Therapy Stage                                                                                                                | Initial Authorization |
| Guideline Type                                                                                                               | Prior Authorization   |



## **Approval Criteria**

**1** - ONE of the following:

**1.1** Submission of medical records (e.g., chart notes) confirming diagnosis of type 2 diabetes mellitus as evidenced by ONE of the following laboratory values

- A1C greater than or equal to 6.5%
- Fasting plasma glucose (FPG) greater than or equal to 126 mg/dL
- 2-hour plasma glucose (PG) greater than or equal to 200 mg/dL during oral glucose tolerance test
- Random plasma glucose greater than or equal to 200 mg/dL in patient with classic symptoms of hyperglycemia or hyperglycemic crisis

**OR**

**1.2** For patients requiring ongoing treatment for type 2 diabetes mellitus (i.e., diagnosed greater than 2 years ago), submission of medical records (e.g., chart notes) confirming diagnosis of type 2 diabetes mellitus

**AND**

**2** - ONE of the following:

**2.1** Failure to ONE of the following therapies for 90 days confirmed by claims history or submission of medical records:

- Steglatro (ertugliflozin) OR Segluromet (ertugliflozin/metformin)
- Dapagliflozin (Farxiga authorized generic)

**OR**

**2.2** History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- Steglatro (ertugliflozin) OR Segluromet (ertugliflozin/metformin)
- Dapagliflozin (Farxiga authorized generic)

|                                                                                                                               |                     |
|-------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name: Brenzavvy, Bexagliflozin, Synjardy, Synjardy XR, Invokamet, Invokamet XR, Xigduo XR, Dapagliflozin/Metformin ER |                     |
| Approval Length                                                                                                               | 12 month(s)         |
| Therapy Stage                                                                                                                 | Reauthorization     |
| Guideline Type                                                                                                                | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p>1 - Documentation of positive clinical response to therapy</p>                             |                     |

|                                                                                                                                                                                                                                                                                                                                                                                                        |                       |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name: Inpefa                                                                                                                                                                                                                                                                                                                                                                                   |                       |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                        | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                          | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                         | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - ONE of the following:</p> <p>1.1 The patient has a diagnosis of heart failure</p> <p style="text-align: center;"><b>OR</b></p> <p>1.2 ALL of the following:</p> <p>1.2.1 Diagnosis of type 2 diabetes mellitus</p> <p style="text-align: center;"><b>AND</b></p> <p>1.2.2 Diagnosis of chronic kidney disease</p> <p style="text-align: center;"><b>AND</b></p> |                       |

**1.2.3** At least ONE additional cardiovascular risk factor such as:

- History of heart failure
- Obesity
- Dyslipidemia
- Hypertension
- Elevated cardiac and inflammatory biomarkers

**AND**

**2** - ONE of the following:

- Failure to dapagliflozin (Farxiga authorized generic) confirmed by claims history or submission of medical records
- History of contraindication or intolerance to dapagliflozin (Farxiga authorized generic) (please specify contraindication or intolerance)

|                                                                                            |                     |
|--------------------------------------------------------------------------------------------|---------------------|
| Product Name: Inpefa                                                                       |                     |
| Approval Length                                                                            | 12 month(s)         |
| Therapy Stage                                                                              | Reauthorization     |
| Guideline Type                                                                             | Prior Authorization |
| <b>Approval Criteria</b><br><br>1 - Documentation of positive clinical response to therapy |                     |

## 2 . Revision History

| Date      | Notes                              |
|-----------|------------------------------------|
| 3/13/2025 | Updated CKD language for Jardiance |

## Short-Acting Opioid Products



### Prior Authorization Guideline

|                       |                                                                                                         |
|-----------------------|---------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-159322                                                                                               |
| <b>Guideline Name</b> | Short-Acting Opioid Products                                                                            |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>Medicaid - Community &amp; State New Jersey (PSI2300)</li> </ul> |

#### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 1/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>Product Name: butorphanol nasal sol, carisoprodol/aspirin/codeine, codeine, acetaminophen w/codeine soln and tabs, Brand Fioricet/codeine, generic butalbital/acetaminophen/caffeine w/codeine, Ascomp/codeine, generic butalbital/aspirin/caffeine w/codeine, morphine supp, tabs and soln, Brand Lortab, hydrocodone/acetaminophen soln, Brand Xodol, generic hydrocodone/acetaminophen tabs, hydrocodone/ibuprofen, Brand Dilaudid, generic hydromorphone, oxycodone caps, soln and conc, Brand Roxicodone, Oxaydo, generic oxycodone tabs, Brand Percocet, Prolate tabs and soln, Nalocet, Endocet, Oxycodone-acetaminophen soln and tabs, generic oxycodone/acetaminophen soln and tabs, oxymorphone, pentazocine w/naloxone, Brand Ultram, Synapryn, generic tramadol, Qdolo, Tramadol soln, Brand Ultracet, generic tramadol/acetaminophen, Nucynta, meperidine, levorphanol, Brand Trezix, generic acetaminophen/caffeine/dihydrocodeine, generic belladonna alkaloids/opium, opium, Apadaz, Benzhydrocodone/acetaminophen, Seglantis, Brand Roxybond, Brand Oxycodone</p> |                                                                                                                                                |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | DUR: Non-cough and cold Opioid Naïve (Not having filled an opioid in the past 60 days) exceeding the 5 day supply limit and/or 50-90MME limit* |

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Prior Authorization |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Opioid naïve patients (defined as not having filled an opioid in the past 60 days) may receive greater than the 5 day supply limit and/or greater than 50 morphine milligram equivalents (MME) based on ALL of the following:</p> <p><b>1.1</b> If the request is for greater than the 5 day supply limit, ONE of the following:</p> <p><b>1.1.1</b> Cancer-related pain (i.e., patients undergoing active cancer treatment; or cancer survivors with chronic pain who have completed cancer treatment, are in clinical remission, or are under cancer surveillance)</p> <p style="text-align: center;"><b>OR</b></p> <p><b>1.1.2</b> End of life care, including hospice care</p> <p style="text-align: center;"><b>OR</b></p> <p><b>1.1.3</b> Palliative care</p> <p style="text-align: center;"><b>OR</b></p> <p><b>1.1.4</b> Sickle cell anemia</p> <p style="text-align: center;"><b>OR</b></p> <p><b>1.1.5</b> BOTH of the following:</p> <p><b>1.1.5.1</b> ONE of the following:</p> <ul style="list-style-type: none"> <li>• Traumatic injury</li> <li>• Post-surgical procedures, excluding dental procedures</li> <li>• Prescriber attests that the patient has received an opioid within the past 60 days</li> </ul> |                     |

**AND**

**1.1.5.2** Prescriber attests if requested for traumatic injury or post-surgical procedure, that based on injury or surgical procedure performed the patient requires greater than a 5 day supply of short-acting opioid to adequately control pain

**AND**

**1.2** If the request is for 50 MME to 90 MME, ONE of the following (NOTE: If the request exceeds 90 MME please skip this section and proceed to the MME Reviews section):

**1.2.1** Diagnosis of ONE of the following:

- Cancer-related pain (i.e., patients undergoing active cancer treatment; or cancer survivors with chronic pain who have completed cancer treatment, are in clinical remission, or are under cancer surveillance)
- End of life pain (including hospice care)
- Palliative care
- Sickle cell anemia

**OR**

**1.2.2** Patient is currently exceeding 50 MME and prescriber attests patient has been on opioids in the past 60 days

**OR**

**1.2.3** Document ALL of the following:

- The diagnosis is associated with the need for pain management with opioids
- If used in patients with medical comorbidities or if used concurrently with a benzodiazepine or other drugs that could potentially cause drug-drug interactions, the prescriber has acknowledged that they have completed an assessment of increased risk for respiratory depression
- The prescriber has acknowledged that they have completed an addiction risk and risk of overdose assessment
- Prescriber attests the patient requires more than 50 MME per day to adequately control pain

|       |                                                                                                                                                                                                                                                                                           |
|-------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Notes | <p>*This section does NOT apply to cough and cold products.</p> <p>**Approval length for cancer-related pain, end of life, palliative care, or sickle cell pain will be issued for 12 months. All other approvals will be issued for the requested duration, not to exceed one month.</p> |
|-------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

Product Name: butorphanol nasal sol, carisoprodol/aspirin/codeine, codeine, acetaminophen w/codeine soln and tabs, Brand Fioricet/codeine, generic butalbital/acetaminophen/caffeine w/codeine, Ascomp/codeine, generic butalbital/aspirin/caffeine w/codeine, morphine supp, tabs and soln, Brand Lortab, hydrocodone/acetaminophen soln, Brand Xodol, generic hydrocodone/acetaminophen tabs, hydrocodone/ibuprofen, Brand Dilaudid, generic hydromorphone, oxycodone caps, soln and conc, Brand Roxicodone, Oxaydo, generic oxycodone tabs, Brand Percocet, Prolate tabs and soln, Nalocet, Endocet, Oxycodone-acetaminophen soln and tabs, generic oxycodone/acetaminophen soln and tabs, oxymorphone, pentazocine w/naloxone, Brand Ultram, Synapryn, generic tramadol, Qdolo, Tramadol soln, Brand Ultracet, generic tramadol/acetaminophen, Nucynta, meperidine, levorphanol, Brand Trezix, generic acetaminophen/caffeine/dihydrocodeine, generic belladonna alkaloids/opium, opium, Apadaz, Benzhydrocodone/acetaminophen, Seglantis, Brand Roxybond, Brand Oxycodone

|                 |                        |
|-----------------|------------------------|
| Diagnosis       | Non-Preferred Reviews* |
| Approval Length | 12 month(s)            |
| Guideline Type  | Prior Authorization    |

### Approval Criteria

#### 1 - ONE of the following:

**1.1** If the request is for tramadol 100 mg (milligram) tablets, the physician has provided rationale for needing to use the 100 mg tramadol tablet instead of two 50 mg tramadol tablets

**OR**

**1.2** If the request is for tramadol 25 mg tablets, the physician has provided rationale why the patient is unable to use half of a 50 mg tramadol tablet

**OR**

#### **1.3** If the request is for Qdolo (tramadol soln), ONE of the following:

**1.3.1** Failure of tramadol 50mg tablets as confirmed by claims history or submission of medical records

**OR**

**1.3.2** History of intolerance or contraindication to tramadol 50mg tablets (please specify intolerance or contraindication)

**OR**

**1.3.3** Patient is unable to swallow a solid dosage form

**OR**

**1.3.4** Patient utilizes a feeding tube for medication administration

**OR**

**1.4** If the request is for another non-preferred medication\*\*, then ONE of the following:

**1.4.1** Failure of at least three unique active ingredients from the preferred short-acting opioids list as confirmed by claims history or submission of medical records

**OR**

**1.4.2** History of intolerance or contraindication to three unique active ingredients from the preferred short-acting opioids list (please specify intolerance or contraindication)

Notes

\*This section does NOT apply to cough and cold products.

\*\*State PDL may be found at the following: <https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html>

Product Name: butorphanol nasal sol, carisoprodol/aspirin/codeine, codeine, acetaminophen w/codeine soln and tabs, Brand Fioricet/codeine, generic butalbital/acetaminophen/caffeine w/codeine, Ascomp/codeine, generic butalbital/aspirin/caffeine w/codeine, morphine supp, tabs and soln, Brand Lortab, hydrocodone/acetaminophen soln, Brand Xodol, generic hydrocodone/acetaminophen tabs, hydrocodone/ibuprofen, Brand Dilaudid, generic hydromorphone, oxycodone caps, soln and conc, Brand Roxicodone, Oxaydo, generic oxycodone tabs, Brand Percocet, Prolate tabs and soln, Nalocet, Endocet, Oxycodone-



|                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                                                                                                                                                                             |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| acetaminophen soln and tabs, generic oxycodone/acetaminophen soln and tabs, oxymorphone, pentazocine w/naloxone, Brand Ultram, Synapryn, generic tramadol, Qdolo, Tramadol soln, Brand Ultracet, generic tramadol/acetaminophen, Nucynta, meperidine, levorphanol, Brand Trezix, generic acetaminophen/caffeine/dihydrocodeine, generic belladonna alkaloids/opium, opium, Apadaz, Benzhydrocodone/acetaminophen, Seglantis, Brand Roxybond, Brand Oxycodone |                                                                                                                                                                                                                                                                                                                                                                             |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Cancer Related Pain/Hospice/End of Life/Sickle Cell Anemia Related Pain Exceeding the 90 MME Cumulative Threshold*                                                                                                                                                                                                                                                          |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                               | Morphine Milligram Equivalents (MME) Reviews**                                                                                                                                                                                                                                                                                                                              |
| <p><b>Approval Criteria</b></p> <p>1 - Patient has ONE of the following:</p> <ul style="list-style-type: none"> <li>• Cancer-related pain (i.e., patients undergoing active cancer treatment; or cancer survivors with chronic pain who have completed cancer treatment, are in clinical remission, or are under cancer surveillance)</li> <li>• End of life diagnosis (hospice care)</li> <li>• Sickle cell anemia related pain</li> </ul>                  |                                                                                                                                                                                                                                                                                                                                                                             |
| Notes                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <p>*This section does NOT apply to cough and cold products.</p> <p>**Approval length will be issued for up to the requested amount for 12 months for cancer-related pain/hospice/end of life/sickle cell anemia related pain. The authorization should be entered for an MME of 9999 so as to prevent future disruptions in therapy if the patient's dose is increased.</p> |

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|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|
| Product Name:butorphanol nasal sol, carisoprodol/aspirin/codeine, codeine, acetaminophen w/codeine soln and tabs, Brand Fioricet/codeine, generic butalbital/acetaminophen/caffeine w/codeine, Ascomp/codeine, generic butalbital/aspirin/caffeine w/codeine, morphine supp, tabs and soln, Brand Lortab, hydrocodone/acetaminophen soln, Brand Xodol, generic hydrocodone/acetaminophen tabs, hydrocodone/ibuprofen, Brand Dilaudid, generic hydromorphone, oxycodone caps, soln and conc, Brand Roxicodone, Oxaydo, generic oxycodone tabs, Brand Percocet, Prolate tabs and soln, Nalocet, Endocet, Oxycodone-acetaminophen soln and tabs, generic oxycodone/acetaminophen soln and tabs, oxymorphone, pentazocine w/naloxone, Brand Ultram, Synapryn, generic tramadol, Qdolo, Tramadol soln, Brand Ultracet, generic tramadol/acetaminophen, Nucynta, meperidine, levorphanol, Brand Trezix, generic acetaminophen/caffeine/dihydrocodeine, generic belladonna alkaloids/opium, opium, Apadaz, Benzhydrocodone/acetaminophen, Seglantis, Brand Roxybond, Brand Oxycodone |                                                                                                                                     |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Non-cancer related pain/non-hospice/non-end of life/non-sickle cell anemia related pain Exceeding the 90 MME Cumulative Threshold * |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Initial Authorization                                                                                                               |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
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| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Morphine Milligram Equivalents (MME)**                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Prescriber attests the patient has been screened for substance abuse/opioid dependence</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Treatment goals are defined and include estimated duration of treatment (must document treatment goals)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - BOTH of the following:</p> <p><b>3.1</b> Patient has been screened for underlying depression and/or anxiety</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3.2</b> If applicable, any underlying conditions have been or will be addressed</p> <p style="text-align: center;"><b>AND</b></p> <p><b>4</b> - BOTH of the following:</p> <ul style="list-style-type: none"> <li>• Patient has tried and failed non-opioid pain medication (document drug name and date of trial)</li> <li>• Opioid medication doses of less than 90 morphine milligram equivalents (MME) have been tried and did not adequately control pain (document drug regimen or MME and dates of therapy)***</li> </ul> |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Notes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | <p>*This section does NOT apply to cough and cold products.</p> <p>**Approval length will be issued for 6 months for non-cancer related pain/non-hospice/non-end of life/non-sickle cell anemia related pain up to the current requested MME plus 90 MME</p> <p>***If the patient has been established on the requested MME dose for at least 30 days and does not meet the medical necessity authorization criteria requirements, a denial should be issued and a maximum 60-</p> |

|  |                                                                          |
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|  | day authorization may be authorized one time for the requested MME dose. |
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| Product Name:butorphanol nasal sol, carisoprodol/aspirin/codeine, codeine, acetaminophen w/codeine soln and tabs, Brand Fioricet/codeine, generic butalbital/acetaminophen/caffeine w/codeine, Ascomp/codeine, generic butalbital/aspirin/caffeine w/codeine, morphine supp, tabs and soln, Brand Lortab, hydrocodone/acetaminophen soln, Brand Xodol, generic hydrocodone/acetaminophen tabs, hydrocodone/ibuprofen, Brand Dilaudid, generic hydromorphone, oxycodone caps, soln and conc, Brand Roxicodone, Oxaydo, generic oxycodone tabs, Brand Percocet, Prolate tabs and soln, Nalocet, Endocet, Oxycodone-acetaminophen soln and tabs, generic oxycodone/acetaminophen soln and tabs, oxymorphone, pentazocine w/naloxone, Brand Ultram, Synapryn, generic tramadol, Qdolo, Tramadol soln, Brand Ultracet, generic tramadol/acetaminophen, Nucynta, meperidine, levorphanol, Brand Trezix, generic acetaminophen/caffeine/dihydrocodeine, generic belladonna alkaloids/opium, opium, Apadaz, Benzhydrocodone/acetaminophen, Seglantis, Brand Roxybond, Brand Oxycodone |                                                                                                                                                                                                                                                                                                                                          |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Non-cancer related pain/non-hospice/non-end of life/non-sickle cell anemia related pain Exceeding the 90 MME Cumulative Threshold*                                                                                                                                                                                                       |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Reauthorization                                                                                                                                                                                                                                                                                                                          |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Morphine Milligram Equivalents (MME)**                                                                                                                                                                                                                                                                                                   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Prescriber attests the patient has been screened for substance abuse/opioid dependence</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Documented rationale for not tapering or discontinuing opioid if treatment goals are not met</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Documented meaningful improvement in pain and function when assessed against treatment goals (Document improvement in function or pain score improvement)***</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                          |
| Notes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <p>*This section does NOT apply to cough and cold products.</p> <p>**Approval length will be issued for 6 months for non-cancer related pain/non-hospice/non-end of life/non-sickle cell anemia related pain up to the current requested MME plus 90 MME</p> <p>***If the patient has been established on the requested MME dose for</p> |

|  |                                                                                                                                                                                                                   |
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|  | at least 30 days and does not meet the medical necessity authorization criteria requirements, a denial should be issued and a maximum 60-day authorization may be authorized one time for the requested MME dose. |
|--|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

Product Name:butorphanol nasal sol, carisoprodol/aspirin/codeine, codeine, acetaminophen w/codeine soln and tabs, Brand Fioricet/codeine, generic butalbital/acetaminophen/caffeine w/codeine, Ascomp/codeine, generic butalbital/aspirin/caffeine w/codeine, morphine supp, tabs and soln, Brand Lortab, hydrocodone/acetaminophen soln, Brand Xodol, generic hydrocodone/acetaminophen tabs, hydrocodone/ibuprofen, Brand Dilaudid, generic hydromorphone, oxycodone caps, soln and conc, Brand Roxicodone, Oxaydo, generic oxycodone tabs, Brand Percocet, Prolate tabs and soln, Nalocet, Endocet, Oxycodone-acetaminophen soln and tabs, generic oxycodone/acetaminophen soln and tabs, oxymorphone, pentazocine w/naloxone, Brand Ultram, Synapryn, generic tramadol, Qdolo, Tramadol soln, Brand Ultracet, generic tramadol/acetaminophen, Nucynta, meperidine, levorphanol, Brand Trezix, generic acetaminophen/caffeine/dihydrocodeine, generic belladonna alkaloids/opium, opium, Apadaz, Benzhydrocodone/acetaminophen, Seglantis, Brand Roxybond, Brand Oxycodone

|                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Diagnosis                                                                                                                                                                                                                                                                                                         | Criteria for Quantity Limit Reviews*                                                                                                                                                                                                                                                                                                                                                           |
| Guideline Type                                                                                                                                                                                                                                                                                                    | Quantity Limit                                                                                                                                                                                                                                                                                                                                                                                 |
| <p><b>Approval Criteria</b></p> <p>1 - The requested dose cannot be achieved by a higher strength formulary product</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - The requested dose is within FDA (Food and Drug Administration) maximum dose per day, where an FDA maximum dose per day exists**</p> |                                                                                                                                                                                                                                                                                                                                                                                                |
| Notes                                                                                                                                                                                                                                                                                                             | <p>*This section does NOT apply to cough and cold products.</p> <p>**Authorization will be issued for:</p> <ul style="list-style-type: none"> <li>• 12 months for cancer-related pain/hospice/sickle cell anemia related pain/end of life related pain</li> <li>• 6 months for non-cancer related pain/non-hospice/non-sickle cell anemia related pain/non-end of life related pain</li> </ul> |

Product Name:Brand Hycodan tab and syrup, generic hydrocodone/homatropine tabs and syrup, Hydromet syrup, Tuzistra XR, hydrocodone polst-chlorphen polst ER, M-END PE, Poly-Tussin AC, Capcof, Pro-Red AC, Histex-AC, Maxi-Tuss CD, promethazine-codeine syrup, promethazine-phenylephrine-codeine syrup (promethazine VC-codeine syrup), Rydex,

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                      |
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| Mar-Cof BP, Mar-Cof CG, Ninjacof-XG, Coditussin AC, M-Clear WC, codeine/guaifenesin soln (Virtussin AC/ALC, Virtussin A/C, Maxi-Tuss AC, GuaiaTussin AC, G Tussin AC, Guaifenesin AC), Tusnel C, Virtussin DAC, Tuxarin ER, Coditussin DAC                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                      |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | DUR: Cough and Cold Opioid Naïve (Not having filled an opioid in the past 60 days) exceeding the 5 day supply limit* |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Prior Authorization                                                                                                  |
| <p><b>Approval Criteria</b></p> <p><b>1 - ONE of the following:</b></p> <p><b>1.1</b> Cancer-related pain (i.e., patients undergoing active cancer treatment; or cancer survivors with chronic pain who have completed cancer treatment, are in clinical remission, or are under cancer surveillance)</p> <p style="text-align: center;"><b>OR</b></p> <p><b>1.2</b> End of life care, including hospice care</p> <p style="text-align: center;"><b>OR</b></p> <p><b>1.3</b> Palliative care</p> <p style="text-align: center;"><b>OR</b></p> <p><b>1.4</b> Sickle cell anemia</p> <p style="text-align: center;"><b>OR</b></p> <p><b>1.5</b> BOTH of the following:</p> <p><b>1.5.1</b> ONE of the following:</p> <ul style="list-style-type: none"> <li>• Traumatic injury</li> <li>• Post-surgical procedures, excluding dental procedures</li> <li>• Prescriber attests that the patient has received an opioid within the past 60 days</li> </ul> |                                                                                                                      |

**AND**

**1.5.2** Prescriber attests if requested for traumatic injury or post-surgical procedure, that based on injury or surgical procedure performed the patient requires greater than a 5 day supply of short-acting opioid to adequately control pain

|       |                                                                                                                                                                                                                   |
|-------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Notes | *Approval length for cancer-related pain, end of life, palliative care, or sickle cell pain will be issued for 12 months. All other approvals will be issued for the requested duration, not to exceed one month. |
|-------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

Product Name: Brand Hycodan tab and syrup, generic hydrocodone/homatropine tabs and syrup, Hydromet syrup, Tuzistra XR, hydrocodone polst-chlorphen polst ER, M-END PE, Poly-Tussin AC, Capcof, Pro-Red AC, Histex-AC, Maxi-Tuss CD, promethazine-codeine syrup, promethazine-phenylephrine-codeine syrup (promethazine VC-codeine syrup), Rydex, Mar-Cof BP, Mar-Cof CG, Ninjacof-XG, Coditussin AC, M-Clear WC, codeine/guaifenesin soln (Virtussin AC/ALC, Virtussin A/C, Maxi-Tuss AC, GuaiaTussin AC, G Tussin AC, Guaifenesin AC), Tusnel C, Virtussin DAC, Tuxarin ER, Coditussin DAC

|           |                                                                   |
|-----------|-------------------------------------------------------------------|
| Diagnosis | Cough and Cold Products Exceeding the 90 MME Cumulative Threshold |
|-----------|-------------------------------------------------------------------|

|                |                                       |
|----------------|---------------------------------------|
| Guideline Type | Morphine Milligram Equivalents (MME)* |
|----------------|---------------------------------------|

**Approval Criteria**

**1** - The prescriber attests they are aware of patient's current opioid therapy and morphine milligram equivalents (MME) dose and feels the treatment with the requested product is medically necessary

|       |                                                                                                                                                    |
|-------|----------------------------------------------------------------------------------------------------------------------------------------------------|
| Notes | *Approval length will be issued for up to 30 days for cough and cold related treatment. The authorization should be entered for the MME requested. |
|-------|----------------------------------------------------------------------------------------------------------------------------------------------------|

Product Name: Brand Hycodan tab and syrup, generic hydrocodone/homatropine tabs and syrup, Hydromet syrup, Tuzistra XR, hydrocodone polst-chlorphen polst ER, M-END PE, Poly-Tussin AC, Capcof, Pro-Red AC, Histex-AC, Maxi-Tuss CD, promethazine-codeine syrup, promethazine-phenylephrine-codeine syrup (promethazine VC-codeine syrup), Rydex, Mar-Cof BP, Mar-Cof CG, Ninjacof-XG, Coditussin AC, M-Clear WC, codeine/guaifenesin soln (Virtussin AC/ALC, Virtussin A/C, Maxi-Tuss AC, GuaiaTussin AC, G Tussin AC, Guaifenesin AC), Tusnel C, Virtussin DAC, Tuxarin ER, Coditussin DAC

|           |                                                       |
|-----------|-------------------------------------------------------|
| Diagnosis | Under the Age of 18 Years for Cough and Cold Products |
|-----------|-------------------------------------------------------|

|                 |           |
|-----------------|-----------|
| Approval Length | 30 Day(s) |
|-----------------|-----------|

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Prior Authorization |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Prescriber attests they are aware of Food and Drug Administration (FDA) labeled contraindications regarding use of opioid containing cough and cold products in patients less than 18 years of age and feels the treatment with the requested product is medically necessary (Document rationale for use)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Patient does not have a comorbid condition that may impact respiratory depression (e.g., asthma or other chronic lung disease, sleep apnea, body mass index &gt; 30)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Patient has tried and failed at least one non-opioid containing cough and cold remedy</p> |                     |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                            |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------|
| Product Name: Brand Hycodan tab and syrup, generic hydrocodone/homatropine tabs and syrup, Hydromet syrup, Tuzistra XR, hydrocodone polst-chlorphen polst ER, M-END PE, Poly-Tussin AC, Capcof, Pro-Red AC, Histex-AC, Maxi-Tuss CD, promethazine-codeine syrup, promethazine-phenylephrine-codeine syrup (promethazine VC-codeine syrup), Rydex, Mar-Cof BP, Mar-Cof CG, Ninjacof-XG, Coditussin AC, M-Clear WC, codeine/guaifenesin soln (Virtussin AC/ALC, Virtussin A/C, Maxi-Tuss AC, Guaiatussin AC, G Tussin AC, Guaifenesin AC), Tusnel C, Virtussin DAC, Tuxarin ER, Coditussin DAC |                                                                            |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Cough and Cold Products Exceeding 120mL per fill and/or 360mL per 30 days* |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 30 days**                                                                  |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Quantity Limit                                                             |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Prescriber attests that a larger quantity is medically necessary</p> <p style="text-align: center;"><b>AND</b></p>                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                            |

**2** - The requested dose is within the Food and Drug Administration (FDA) maximum dose per day, where an FDA maximum dose per day exists

|       |                                                                                                                                                                                                                                                         |
|-------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Notes | <p>*Quantity Limit Rules in place:</p> <ul style="list-style-type: none"> <li>• 120mL/fill</li> <li>• 360mL/30 days</li> </ul> <p>**Authorization will be issued for up to 30 days. The authorization should be entered for the quantity requested.</p> |
|-------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

Product Name: Brand Hycodan tab and syrup, generic hydrocodone/homatropine tabs and syrup, Hydromet syrup, Tuzistra XR, hydrocodone polst-chlorphen polst ER, M-END PE, Poly-Tussin AC, Capcof, Pro-Red AC, Histex-AC, Maxi-Tuss CD, promethazine-codeine syrup, promethazine-phenylephrine-codeine syrup (promethazine VC-codeine syrup), Rydex, Mar-Cof BP, Mar-Cof CG, Ninjacof-XG, Coditussin AC, M-Clear WC, codeine/guaifenesin soln (Virtussin AC/ALC, Virtussin A/C, Maxi-Tuss AC, Guaiatussin AC, G Tussin AC, Guaifenesin AC), Tusnel C, Virtussin DAC, Tuxarin ER, Coditussin DAC

|                 |                                       |
|-----------------|---------------------------------------|
| Diagnosis       | Non-Preferred Cough and Cold Products |
| Approval Length | 30 Day(s)                             |
| Guideline Type  | Prior Authorization                   |

### Approval Criteria

**1** - If the request is for a non-preferred\* medication, then ONE of the following:

**1.1** Failure of at least three unique active ingredients from the preferred cough and cold products list as confirmed by claims history or submission of medical records

**OR**

**1.2** History of intolerance or contraindication to at least three unique active ingredients from the preferred cough and cold products list (please specify intolerance or contraindication)

|       |                                                                                                                                                                                                                                                                                               |
|-------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Notes | *State PDL may be found at the following: <a href="https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html</a> |
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## 2 . Revision History



UnitedHealthcare Community Plan of New Jersey – Clinical Pharmacy Guidelines

| Date      | Notes                                                                                                                                                                                             |
|-----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 11/6/2024 | Added hydrocodone/acetaminophen 10/325 soln removed acetaminophen/caffeine/dihydrocodeine 325-30-16mg. Updated Roxybond GPIs and added Brand oxycodone abuse deter GPIs. Updated cancer language. |

Signifor



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-117468                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Guideline Name</b> | Signifor                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>•</li> <li>•</li> <li>•</li> <li>•</li> <li>•</li> <li>•</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 1/1/2023 |
|-----------------|----------|

## 1 . Criteria

|                        |                       |
|------------------------|-----------------------|
| Product Name: Signifor |                       |
| Approval Length        | 12 month(s)           |
| Therapy Stage          | Initial Authorization |

|                                                                                                                                                                                                                                                                                                                                                                                                                                         |                     |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                          | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of endogenous Cushing's disease (i.e., hypercortisolism is not a result of chronic administration of high dose glucocorticoids)</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - One of the following:</p> <ul style="list-style-type: none"> <li>Pituitary surgery has not been curative for the patient</li> <li>Patient is not a candidate for pituitary surgery</li> </ul> |                     |

|                                                                                                            |                     |
|------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Signifor                                                                                      |                     |
| Approval Length                                                                                            | 12 month(s)         |
| Therapy Stage                                                                                              | Reauthorization     |
| Guideline Type                                                                                             | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p>1 - Documentation of positive clinical response to Signifor therapy</p> |                     |

## 2 . Revision History

| Date       | Notes                                                     |
|------------|-----------------------------------------------------------|
| 11/30/2022 | Updated Markets in Scope. No changes to clinical criteria |

Siliq



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-208187                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Guideline Name</b> | Siliq                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 4/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                    |                       |
|--------------------|-----------------------|
| Product Name:Siliq |                       |
| Approval Length    | 12 month(s)           |
| Therapy Stage      | Initial Authorization |
| Guideline Type     | Prior Authorization   |
|                    |                       |

## **Approval Criteria**

**1** - Diagnosis of chronic moderate to severe plaque psoriasis

**AND**

**2** - Patient is not receiving Siliq in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

**AND**

**3** - Prescribed by or in consultation with a dermatologist

**AND**

**4** - One of the following:

**4.1** Patient is currently on Siliq therapy as confirmed by claims history or submitted medical records

**OR**

**4.2** All of the following:

**4.2.1** One of the following:

**4.2.1.1** All of the following:

**4.2.1.1.1** Greater than or equal to 3% body surface area involvement, palmoplantar, facial, or genital involvement, or severe scalp psoriasis

**AND**

**4.2.1.1.2** One of the following:

- Failure of ONE of the following topical therapy classes as confirmed by claims history or submitted medical records: Corticosteroids (e.g., betamethasone, clobetasol, desonide), Vitamin D analogs (e.g., calcitriol, calcipotriene), Tazarotene, Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus), Anthralin, Coal tar
- History of intolerance or contraindication to ALL of the following topical therapy classes (please specify intolerance or contraindication): Corticosteroids (e.g., betamethasone, clobetasol, desonide), Vitamin D analogs (e.g., calcitriol, calcipotriene), Tazarotene, Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus), Anthralin, Coal tar

**AND**

**4.2.1.1.3** One of the following:

- Failure of a 3 month trial of methotrexate, at maximally indicated dose, confirmed by claims history or submitted medical records
- History of intolerance or contraindication to methotrexate (please specify intolerance or contraindication)

**OR**

**4.2.1.2** Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of plaque psoriasis as confirmed by claims history or submission of medical records [e.g., Cimzia (certolizumab), adalimumab, Otezla (apremilast), Skyrizi (risankizumab-rzaa), ustekinumab, Tremfya (guselkumab)]

**AND**

**4.2.2** One of the following:

**4.2.2.1** Failure to TWO of the following preferred products, confirmed by claims history or submitted medical records:

- One of the preferred adalimumab products\*
- Enbrel (etanercept)
- One of the preferred ustekinumab products\*

**OR**

**4.2.2.2** History of intolerance or contraindication to ALL of the following preferred products (please specify intolerance or contraindication):

- One of the preferred adalimumab products\*
- Enbrel (etanercept)
- One of the preferred ustekinumab products\*

**AND**

**4.2.3** One of the following:

**4.2.3.1** Failure to Cosentyx (secukinumab) as confirmed by claims history or submitted medical records

**OR**

**4.2.3.2** History of contraindication or intolerance to Cosentyx (secukinumab) (please specify contraindication or intolerance)

|       |                              |
|-------|------------------------------|
| Notes | *See PDL links in Background |
|-------|------------------------------|

Product Name:Siliq

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                 |
|---------------|-----------------|
| Therapy Stage | Reauthorization |
|---------------|-----------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

### Approval Criteria

**1** - Documentation of positive clinical response to Siliq therapy

**AND**

**2** - Patient is not receiving Siliq in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

## 2 . Background

| Benefit/Coverage/Program Information                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p><b>PDL Links</b></p> <p>CO: <a href="https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html</a></p> <p>HI: <a href="https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html</a></p> <p>MD: <a href="https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-cp-pharmacy.html</a></p> <p>NJ: <a href="https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html</a></p> <p>NM: <a href="https://www.uhcprovider.com/en/health-plans-by-state/new-mexico-health-plans/nm-comm-plan-home/nm-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/new-mexico-health-plans/nm-comm-plan-home/nm-cp-pharmacy.html</a></p> <p>NY/NY EPP: <a href="https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html</a></p> <p>PA CHIP: <a href="https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP">https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP</a></p> <p>RI: <a href="https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html</a></p> |

## 3 . Revision History

| Date     | Notes                                                                                                                                                                                                                                                  |
|----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 3/4/2025 | Updated formularies. Removed reference to brand Stelara throughout. Removed Ilumya step in PsO section and added preferred ustekinumab as step therapy option. Updated note to reference PDL links in background. Added NM to PDL links in background. |



Simponi



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-208189                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Guideline Name</b> | Simponi                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 4/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                       |                           |
|-----------------------|---------------------------|
| Product Name: Simponi |                           |
| Diagnosis             | Rheumatoid Arthritis (RA) |
| Approval Length       | 12 month(s)               |
| Therapy Stage         | Initial Authorization     |
| Guideline Type        | Prior Authorization       |

### **Approval Criteria**

**1** - Diagnosis of moderately to severely active rheumatoid arthritis (RA)

**AND**

**2** - Patient is NOT receiving Simponi in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

**AND**

**3** - Prescribed by or in consultation with a rheumatologist

**AND**

**4** - ONE of the following:

**4.1** Patient is currently on Simponi therapy as confirmed by claims history or submission of medical records

**OR**

**4.2** BOTH of the following:

**4.2.1** ONE of the following:

**4.2.1.1** Failure to a 3 month trial of ONE non-biologic DMARD (e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine) at maximally indicated doses, confirmed by claims history or submitted medical records

**OR**

**4.2.1.2** History of intolerance or contraindication to ONE non-biologic DMARD (e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine) (please specify intolerance or contraindication)

**OR**

**4.2.1.3** Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of rheumatoid arthritis as confirmed by claims history or submission of medical records [e.g., Cimzia (certolizumab), adalimumab, Olumiant (baricitinib), Rinvoq (upadacitinib), Xeljanz/Xeljanz XR (tofacitinib)]

**AND**

**4.2.2** ONE of the following:

- Failure to THREE of the following as confirmed by claims history or submitted medical records: One of the preferred adalimumab products\*, Enbrel (etanercept), Olumiant (baricitinib), Tyenne (tocilizumab-aazg)
- History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication): One of the preferred adalimumab products\*, Enbrel (etanercept), Olumiant (baricitinib), Tyenne (tocilizumab-aazg)

Notes

\*See PDL links in Background

|                                                                                                                                                                                                                                                                                                                                                                                                                              |                       |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name: Simponi                                                                                                                                                                                                                                                                                                                                                                                                        |                       |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                    | Psoriatic Arthritis   |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                              | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                               | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of active psoriatic arthritis</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Patient is NOT receiving Simponi in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz</p> |                       |

(ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

**AND**

**3** - Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Dermatologist

**AND**

**4** - ONE of the following:

**4.1** Patient is currently on Simponi therapy as confirmed by claims history or submission of medical records

**OR**

**4.2** BOTH of the following:

**4.2.1** ONE of the following:

**4.2.1.1** Failure to a 3 month trial of methotrexate at maximally indicated dose, confirmed by claims history or submitted medical records

**OR**

**4.2.1.2** History of intolerance or contraindication to methotrexate (please specify intolerance or contraindication)

**OR**

**4.2.1.3** Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of psoriatic arthritis as confirmed by claims history or submission of medical records [e.g., Cimzia (certolizumab), adalimumab, ustekinumab, Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), Otezla (apremilast), Rinvoq (upadacitinib)]

**AND**

**4.2.2** BOTH of the following:

**4.2.2.1** ONE of the following:

- Failure to TWO of the following as confirmed by claims history or submitted medical records: One of the preferred adalimumab products\*, Enbrel (etanercept), One of the preferred ustekinumab products\*
- History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication): One of the preferred adalimumab products\*, Enbrel (etanercept), One of the preferred ustekinumab products\*

**AND**

**4.2.2.2** ONE of the following:

- Failure to Cosentyx (secukinumab) as confirmed by claims history or submitted medical records
- History of intolerance or contraindication to Cosentyx (secukinumab) (please specify intolerance or contraindication)

Notes

\*See PDL links in Background

|                                                                                                         |                        |
|---------------------------------------------------------------------------------------------------------|------------------------|
| Product Name: Simponi                                                                                   |                        |
| Diagnosis                                                                                               | Ankylosing Spondylitis |
| Approval Length                                                                                         | 12 month(s)            |
| Therapy Stage                                                                                           | Initial Authorization  |
| Guideline Type                                                                                          | Prior Authorization    |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of active ankylosing spondylitis</p> <p><b>AND</b></p> |                        |

**2** - Patient is NOT receiving Simponi in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

**AND**

**3** - Prescribed by or in consultation with a rheumatologist

**AND**

**4** - ONE of the following:

**4.1** Patient is currently on Simponi therapy as confirmed by claims history or submission of medical records

**OR**

**4.2** BOTH of the following:

**4.2.1** ONE of the following:

**4.2.1.1** Failure to TWO NSAIDs (non-steroidal anti-inflammatory drugs) (e.g., ibuprofen, naproxen) at maximally indicated doses, each used for at least 4 weeks confirmed by claims history or submitted medical records

**OR**

**4.2.1.2** History of intolerance or contraindication to TWO NSAIDs (please specify intolerance or contraindication)

**OR**

**4.2.1.3** Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of ankylosing spondylitis as confirmed by claims history or submission of medical records [e.g., Cimzia (certolizumab), adalimumab, Xeljanz/Xeljanz XR (tofacitinib), Rinvoq (upadacitinib)]

**AND**

**4.2.2** BOTH of the following:

**4.2.2.1** ONE of the following:

- Failure to BOTH of the following as confirmed by claims history or submitted medical records: One of the preferred adalimumab products\*, Enbrel (etanercept)
- History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication): One of the preferred adalimumab products\*, Enbrel (etanercept)

**AND**

**4.2.2.2** ONE of the following:

- Failure to Cosentyx (secukinumab) as confirmed by claims history or submitted medical records
- History of intolerance or contraindication to Cosentyx (secukinumab) (please specify intolerance or contraindication)

|       |                              |
|-------|------------------------------|
| Notes | *See PDL links in Background |
|-------|------------------------------|

|                                                                                                                            |                       |
|----------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name: Simponi                                                                                                      |                       |
| Diagnosis                                                                                                                  | Ulcerative Colitis    |
| Approval Length                                                                                                            | 12 month(s)           |
| Therapy Stage                                                                                                              | Initial Authorization |
| Guideline Type                                                                                                             | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of moderately to severely active ulcerative colitis</p> <p><b>AND</b></p> |                       |

**2** - Patient is NOT receiving Simponi in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Orenzia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), ustekinumab, Skyrizi (risankizumab)]

**AND**

**3** - Prescribed by or in consultation with a gastroenterologist

**AND**

**4** - ONE of the following:

**4.1** Patient is currently on Simponi therapy as confirmed by claims history or submission of medical records

**OR**

**4.2** BOTH of the following:

**4.2.1** ONE of the following:

**4.2.1.1** Patient has had prior or concurrent inadequate response to a therapeutic course of oral corticosteroids and/or immunosuppressants (e.g., azathioprine, 6-mercaptopurine) as confirmed by claims history or submitted medical records

**OR**

**4.2.1.2** Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of ulcerative colitis as confirmed by claims history or submission of medical records [e.g., adalimumab, ustekinumab, Xeljanz (tofacitinib), Rinvoq (upadacitinib)]

**AND**

**4.2.2** ONE of the following:

- Failure to one of the following as confirmed by claims history or submitted medical records: One of the preferred adalimumab products\*, One of the preferred ustekinumab products\*



|                                                                                                                                                                                                                                                               |                              |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|
| <ul style="list-style-type: none"> <li>History of intolerance or contraindication to both of the following (please specify intolerance or contraindication): One of the preferred adalimumab products*, One of the preferred ustekinumab products*</li> </ul> |                              |
| Notes                                                                                                                                                                                                                                                         | *See PDL links in Background |

| Product Name:Simponi                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                            |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------|
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Rheumatoid Arthritis (RA), Psoriatic Arthritis, Ankylosing Spondylitis, Ulcerative Colitis |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 12 month(s)                                                                                |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Reauthorization                                                                            |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Prior Authorization                                                                        |
| <p><b>Approval Criteria</b></p> <p>1 - Documentation of positive clinical response to Simponi therapy</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Patient is NOT receiving Simponi in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]*</p> |                                                                                            |
| Notes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | * Examples of drug(s) may not be applicable based on the requested indication.             |

## 2 . Background

| Benefit/Coverage/Program Information |
|--------------------------------------|
| PDL Links                            |

CO: <https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html>

HI: <https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html>

MD: <https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-cp-pharmacy.html>

NJ: <https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html>

NM: <https://www.uhcprovider.com/en/health-plans-by-state/new-mexico-health-plans/nm-comm-plan-home/nm-cp-pharmacy.html>

NY: <https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html>

PA: <https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP>

RI: <https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html>

### 3 . Revision History

| Date     | Notes                                                                                                                                                             |
|----------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 3/4/2025 | Updated formularies. Added ustekinumab as a step therapy option in PsA and UC. Replaced Stelara with ustekinumab throughout. Added NM to PDL links in background. |

Sivextro



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-398256                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Guideline Name</b> | Sivextro                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Pennsylvania (ACUPA)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 10/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                               |                                    |
|-------------------------------|------------------------------------|
| Product Name:Sivextro tablets |                                    |
| Diagnosis                     | Skin and Skin Structure Infections |
| Approval Length               | 1 month(s)                         |

| Guideline Type | Prior Authorization                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                | <p><b>Approval Criteria</b></p> <p><b>1</b> - For continuation of therapy upon hospital discharge</p> <p style="text-align: center;"><b>OR</b></p> <p><b>2</b> - As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication</p> <p style="text-align: center;"><b>OR</b></p> <p><b>3</b> - ALL of the following:</p> <p><b>3.1</b> Diagnosis of acute bacterial skin and skin structure infection (including diabetic foot infections)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3.2</b> ONE of the following:</p> <p><b>3.2.1</b> Infection is caused by methicillin-resistant Staphylococcus aureus (MRSA) documented by culture and sensitivity report</p> <p style="text-align: center;"><b>OR</b></p> <p><b>3.2.2</b> Presence of MRSA infection is likely and empiric treatment is warranted</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3.3</b> ONE of the following:</p> <p><b>3.3.1</b> Failure of linezolid (generic Zyvox) confirmed by claims history or submitted medical records</p> |

**OR**

**3.3.2** History of intolerance or contraindication to linezolid (generic Zyvox) (please specify intolerance or contraindication)

**AND**

**3.4** ONE of the following:

**3.4.1** Failure of ONE of the following confirmed by claims history or submitted medical records:

- Sulfamethoxazole-trimethoprim (SMX-TMP)
- A tetracycline
- Clindamycin

**OR**

**3.4.2** History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication):

- Sulfamethoxazole-trimethoprim (SMX-TMP)
- A tetracycline
- Clindamycin

**OR**

**4** - ALL of the following:

**4.1** Diagnosis of acute bacterial skin and skin structure infection (including diabetic foot infections)

**AND**

**4.2** Infection caused by an organism that is confirmed to be or likely to be susceptible to treatment with Sivextro

**AND**

**4.3** ONE of the following:

**4.3.1** Failure of linezolid (generic Zyvox) confirmed by claims history or submitted medical records

**OR**

**4.3.2** History of intolerance or contraindication to linezolid (generic Zyvox) (please specify intolerance or contraindication)

**AND**

**4.4** ONE of the following:

**4.4.1** Failure of TWO of the following confirmed by claims history or submitted medical records:

- A penicillin
- A cephalosporin
- A tetracycline
- Clindamycin
- Sulfamethoxazole-trimethoprim (SMX-TMP)
- A fluoroquinolone

**OR**

**4.4.2** History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication):

- A Penicillin
- A cephalosporin
- A tetracycline
- Clindamycin
- Sulfamethoxazole-trimethoprim (SMX-TMP)
- A fluoroquinolone

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                             |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| Product Name:Sivextro tablets                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                             |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Off-Label Uses                                                              |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Based on provider and IDSA recommended treatment durations, up to 6 months. |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Prior Authorization                                                         |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - For continuation of therapy upon hospital discharge</p> <p style="text-align: center;"><b>OR</b></p> <p><b>2</b> - As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication</p> <p style="text-align: center;"><b>OR</b></p> <p><b>3</b> - BOTH of the following:</p> <p><b>3.1</b> The drug has been recognized for treatment of the indication by the Infectious Diseases Society of America (IDSA)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3.2</b> ONE of the following:</p> <p><b>3.2.1</b> Failure of linezolid (generic Zyvox) confirmed by claims history or submitted medical records, if susceptibility is confirmed by culture</p> <p style="text-align: center;"><b>OR</b></p> <p><b>3.2.2</b> History of intolerance or contraindication to linezolid (generic Zyvox), if susceptibility is confirmed by culture (please specify intolerance or contraindication)</p> |                                                                             |

## 2 . Revision History

| Date      | Notes                                      |
|-----------|--------------------------------------------|
| 9/18/2025 | Combined formularies. Updated auth length. |



Skyclarys



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-127205                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Guideline Name</b> | Skyclarys                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 8/1/2023 |
|-----------------|----------|

## 1 . Criteria

|                        |                       |
|------------------------|-----------------------|
| Product Name:Skyclarys |                       |
| Approval Length        | 12 month(s)           |
| Therapy Stage          | Initial Authorization |
| Guideline Type         | Prior Authorization   |
|                        |                       |

**Approval Criteria**

**1** - Diagnosis of Friedreich's ataxia

**AND**

**2** - Confirmed presence of a mutation in the frataxin (FXN) gene

**AND**

**3** - Prescribed by, or in consultation with, one of the following:

- Neurologist
- Neurogeneticist
- Physical Medicine and Rehabilitation physician (i.e., physiatrist)

**Product Name:**Skyclarys

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                 |
|---------------|-----------------|
| Therapy Stage | Reauthorization |
|---------------|-----------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

**1** - Documentation of positive clinical response to Skyclarys therapy

**AND**

**2** - Prescribed by, or in consultation with, one of the following:

- Neurologist
- Neurogeneticist
- Physical Medicine and Rehabilitation physician (i.e., physiatrist)

## 2 . Revision History

| Date      | Notes         |
|-----------|---------------|
| 6/28/2023 | New guideline |

Skyrizi



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-398203                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Guideline Name</b> | Skyrizi                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 10/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                      |                       |
|----------------------|-----------------------|
| Product Name:Skyrizi |                       |
| Diagnosis            | Plaque Psoriasis      |
| Approval Length      | 12 month(s)           |
| Therapy Stage        | Initial Authorization |
| Guideline Type       | Prior Authorization   |

## **Approval Criteria**

**1** - Diagnosis of moderate to severe plaque psoriasis

**AND**

**2** - Patient is NOT receiving Skyrizi in combination with another targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Ilumya (tildrakizumab), Otezla (apremilast), Siliq (brodalumab), Sotyktu (deucravacitinib), Taltz (ixekizumab), Tremfya (guselkumab), ustekinumab]

**AND**

**3** - Prescribed by or in consultation with a dermatologist

**AND**

**4** - One of the following:

**4.1** Patient is currently on Skyrizi therapy as confirmed by claims history or submission of medical records

**OR**

**4.2** ALL of the following:

**4.2.1** One of the following:

**4.2.1.1** Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of plaque psoriasis as confirmed by claims history or submission of medical records [e.g., adalimumab, Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Otezla (apremilast), Sotyktu (deucravacitinib), Tremfya (guselkumab), ustekinumab]

**OR**

**4.2.1.2** All of the following:

**4.2.1.2.1** Greater than or equal to 3% body surface area involvement, palmoplantar, facial, or genital involvement, or severe scalp psoriasis

**AND**

**4.2.1.2.2** One of the following:

- Failure to ONE of the following topical therapy classes confirmed by claims history or submission of medical records: Corticosteroids (e.g., betamethasone, clobetasol, desonide), Vitamin D analogs (e.g., calcitriol, calcipotriene), Tazarotene, Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus), Anthralin, Coal tar
- History of intolerance or contraindication to ALL of the following topical therapies classes (please specify intolerance or contraindication): Corticosteroids (e.g., betamethasone, clobetasol, desonide), Vitamin D analogs (e.g., calcitriol, calcipotriene), Tazarotene, Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus), Anthralin, Coal tar

**AND**

**4.2.1.2.3** One of the following:

- Failure to a 3 month trial of methotrexate at maximally indicated dose confirmed by claims history or submission of medical records
- History of intolerance or contraindication to methotrexate (please specify intolerance or contraindication)

**AND**

**4.2.2** One of the following:

**4.2.2.1** Failure to TWO of the following preferred\* products, confirmed by claims history or submitted medical records:

- One of the preferred adalimumab products
- Enbrel (etanercept)
- One of the preferred ustekinumab products

**OR**

**4.2.2.2** History of intolerance or contraindication to ALL of the following preferred\* products (please specify intolerance or contraindication):

- One of the preferred adalimumab products
- Enbrel (etanercept)
- One of the preferred ustekinumab products

**AND**

**4.2.3** One of the following:

- Failure to Cosentyx (secukinumab) confirmed by claims history or submission of medical records
- History of intolerance or contraindication to Cosentyx (secukinumab) (please specify intolerance or contraindication)

|       |                              |
|-------|------------------------------|
| Notes | *See PDL links in Background |
|-------|------------------------------|

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                       |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Skyrizi                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                       |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Psoriatic Arthritis   |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of active psoriatic arthritis</p> <p><b>AND</b></p> <p><b>2</b> - Patient is NOT receiving Skyrizi in combination with another targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Ilumya (tildrakizumab), Otezla (apremilast), Siliq (brodalumab), Sotyktu (deucravacitinib), Taltz (ixekizumab), Tremfya (guselkumab), ustekinumab]</p> |                       |

**AND**

**3** - Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Dermatologist

**AND**

**4** - One of the following:

**4.1** Patient is currently on Skyrizi therapy as confirmed by claims history or submission of medical records

**OR**

**4.2** BOTH of the following:

**4.2.1** One of the following:

- Failure to a 3 month trial of methotrexate at the maximally indicated dose confirmed by claims history or submission of medical records
- History of intolerance or contraindication to methotrexate (please specify intolerance or contraindication)
- Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of psoriatic arthritis as confirmed by claims history or submission of medical records [e.g., adalimumab, Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Otezla (apremilast), Rinvoq (upadacitinib), Simponi (golimumab), Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), ustekinumab]

**AND**

**4.2.2** Both of the following:

**4.2.2.1** One of the following:

- Failure to TWO of the following as confirmed by claims history or submission of medical records: One of the preferred adalimumab products\*, Enbrel (etanercept), One of the preferred ustekinumab products\*



- History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication): One of the preferred adalimumab products\*, Enbrel (etanercept), One of the preferred ustekinumab products\*

**AND**

**4.2.2.2** One of the following:

- Failure to Cosentyx (secukinumab) as confirmed by claims history or submission of medical records
- History of intolerance or contraindication to Cosentyx (secukinumab) (please specify intolerance or contraindication)

|       |                              |
|-------|------------------------------|
| Notes | *See PDL links in Background |
|-------|------------------------------|

Product Name:Skyrizi

|                 |                       |
|-----------------|-----------------------|
| Diagnosis       | Crohn's Disease       |
| Approval Length | 12 month(s)           |
| Therapy Stage   | Initial Authorization |
| Guideline Type  | Prior Authorization   |

**Approval Criteria**

**1** - Diagnosis of moderately to severely active Crohn's disease

**AND**

**2** - One of the following:

**2.1** Patient has been approved for loading dose of Skyrizi under an active UnitedHealthcare medical benefit prior authorization for the treatment of moderately to severely active Crohn's disease

**OR**

**2.2** Patient is currently on Skyrizi therapy for moderately to severely active Crohn's disease as confirmed by claims history or submission of medical records

**AND**

**3** - Patient is NOT receiving Skyrizi in combination with another targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Ilumya (tildrakizumab), Otezla (apremilast), Siliq (brodalumab), Sotyktu (deucravacitinib), Taltz (ixekizumab), Tremfya (guselkumab), ustekinumab]

**AND**

**4** - Prescribed by or in consultation with a gastroenterologist

|                                                                                                                                                                                                                                                                                                                                                                                                               |                         |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|
| Product Name:Skyrizi                                                                                                                                                                                                                                                                                                                                                                                          |                         |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                     | Ulcerative Colitis (UC) |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                               | 12 month(s)             |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                 | Initial Authorization   |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                | Prior Authorization     |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of moderately to severely active ulcerative colitis</p> <p><b>AND</b></p> <p><b>2</b> - One of the following:</p> <p><b>2.1</b> Patient has been approved for loading dose of Skyrizi under an active UnitedHealthcare medical benefit prior authorization for the treatment of moderately to severely active ulcerative colitis</p> <p><b>OR</b></p> |                         |

**2.2** Patient is currently on Skyrizi therapy for moderately to severely active ulcerative colitis as confirmed by claims history or submission of medical records

**AND**

**3** - Patient is NOT receiving Skyrizi in combination with another targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Ilumya (tildrakizumab), Otezla (apremilast), Siliq (brodalumab), Sotyktu (deucravacitinib), Taltz (ixekizumab), Tremfya (guselkumab), ustekinumab]

**AND**

**4** - Prescribed by or in consultation with a gastroenterologist

| Product Name:Skyrizi                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                            |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------|
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Plaque Psoriasis, Psoriatic Arthritis (PsA), Crohn's Disease (CD), Ulcerative Colitis (UC) |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 12 month(s)                                                                                |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Reauthorization                                                                            |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Prior Authorization                                                                        |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of positive clinical response to Skyrizi therapy</p> <p><b>AND</b></p> <p><b>2</b> - Patient is NOT receiving Skyrizi in combination with another targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Ilumya (tildrakizumab), Otezla (apremilast), Siliq (brodalumab), Sotyktu (deucravacitinib), Taltz (ixekizumab), Tremfya (guselkumab), ustekinumab]*</p> |                                                                                            |
| Notes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | * Examples of drug(s) may not be applicable based on the requested indication.             |

## 2 . Background

| Benefit/Coverage/Program Information                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p><b>PDL Links</b></p> <p>CO: <a href="https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html</a></p> <p>HI: <a href="https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html</a></p> <p>MD: <a href="https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-cp-pharmacy.html</a></p> <p>NJ: <a href="https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html</a></p> <p>NM: <a href="https://www.uhcprovider.com/en/health-plans-by-state/new-mexico-health-plans/nm-comm-plan-home/nm-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/new-mexico-health-plans/nm-comm-plan-home/nm-cp-pharmacy.html</a></p> <p>NY: <a href="https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html</a></p> <p>PA: <a href="https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP">https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP</a></p> <p>RI: <a href="https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html</a></p> |

## 3 . Revision History

| Date      | Notes                                                           |
|-----------|-----------------------------------------------------------------|
| 9/15/2025 | Updated drug examples and medical benefit loading dose language |

Sohonos



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-143178                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Guideline Name</b> | Sohonos                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• </li> <li>• </li> <li>• </li> <li>• </li> <li>• </li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 4/1/2024 |
|-----------------|----------|

## 1 . Criteria

|                      |                       |
|----------------------|-----------------------|
| Product Name:Sohonos |                       |
| Approval Length      | 12 month(s)           |
| Therapy Stage        | Initial Authorization |

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Prior Authorization |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of fibrodysplasia ossificans progressiva (FOP)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Diagnosis has been confirmed by the presence of a mutation in the activin receptor IA (ACVR1) gene</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - ONE of the following:</p> <p><b>3.1</b> BOTH of the following:</p> <ul style="list-style-type: none"> <li>• Patient is female</li> <li>• Patient is 8 years of age or older</li> </ul> <p style="text-align: center;"><b>OR</b></p> <p><b>3.2</b> BOTH of the following:</p> <ul style="list-style-type: none"> <li>• Patient is male</li> <li>• Patient is 10 years of age or older</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>4</b> - Sohonos is being used to reduce the volume of new heterotopic ossification (HO)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>5</b> - Prescribed by or in consultation with an FOP expert (e.g., endocrinologist, geneticist, pediatric orthopedist, pediatric rheumatologist)</p> |                     |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                     |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Sohonos                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                     |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 12 month(s)         |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of positive clinical response [e.g., reduction in new HO (heterotopic ossification) volume, improved CAJIS (Cumulative Analogue Joint Involvement Scale) and FOP-PFQ (Fibrodysplasia Ossificans Progressiva-Physical Function Questionnaire) scores, improved quality of life]</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Prescribed by or in consultation with an FOP expert (e.g., endocrinologist, geneticist, pediatric orthopedist, pediatric rheumatologist)</p> |                     |

## 2 . Revision History

| Date      | Notes         |
|-----------|---------------|
| 2/21/2024 | New guideline |



Somavert



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-375410                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Guideline Name</b> | Somavert                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Pennsylvania (ACUPA)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 10/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                        |                       |
|------------------------|-----------------------|
| Product Name: Somavert |                       |
| Approval Length        | 12 month(s)           |
| Therapy Stage          | Initial Authorization |

| Guideline Type | Prior Authorization                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                | <p><b>Approval Criteria</b></p> <p><b>1 - ALL of the following:</b></p> <p><b>1.1</b> Diagnosis of acromegaly confirmed by ONE of the following:</p> <p><b>1.1.1</b> Serum GH (growth hormone) level greater than 1 ng/mL (nanogram/milliliter) after a 2-hour oral glucose tolerance test (OGTT) at time of diagnosis</p> <p style="text-align: center;"><b>OR</b></p> <p><b>1.1.2</b> Elevated serum IGF-1 (insulin-like growth factor-1) levels (above the age and gender adjusted normal range as provided by the physician's lab) at time of diagnosis</p> <p style="text-align: center;"><b>AND</b></p> <p><b>1.2</b> ONE of the following:</p> <p><b>1.2.1</b> Inadequate response to ONE of the following:</p> <ul style="list-style-type: none"> <li>• Surgery</li> <li>• Radiation therapy</li> <li>• Dopamine agonist (e.g., bromocriptine, cabergoline) therapy</li> </ul> <p style="text-align: center;"><b>OR</b></p> <p><b>1.2.2</b> NOT a candidate for any of the following:</p> <ul style="list-style-type: none"> <li>• Surgery</li> <li>• Radiation therapy</li> <li>• Dopamine agonist (e.g., bromocriptine, cabergoline) therapy</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>1.3</b> Inadequate response, intolerance, or contraindication to a long-acting somatostatin analog [e.g., Sandostatin LAR (octreotide), Somatuline Depot (lanreotide)]</p> |

**OR**

**2** - Patient is currently on Somavert therapy for acromegaly

|                                                                                                                                                     |                     |
|-----------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Somavert                                                                                                                               |                     |
| Approval Length                                                                                                                                     | 12 month(s)         |
| Therapy Stage                                                                                                                                       | Reauthorization     |
| Guideline Type                                                                                                                                      | Prior Authorization |
| <b>Approval Criteria</b><br><br><b>1</b> - Documentation of positive clinical response to Somavert therapy (e.g., age-normalized serum IGF-1 level) |                     |

## 2 . Revision History

| Date      | Notes                                                                                                                                                                 |
|-----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 8/25/2025 | Combined formularies. Minor grammatical update from "2 hour" to "2-hour" in initial auth section (no changes to clinical intent). No other changes to guideline made. |

Sotyktu



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-208193                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Guideline Name</b> | Sotyktu                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 4/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                      |                       |
|----------------------|-----------------------|
| Product Name:Sotyktu |                       |
| Diagnosis            | Plaque Psoriasis      |
| Approval Length      | 12 month(s)           |
| Therapy Stage        | Initial Authorization |
| Guideline Type       | Prior Authorization   |

## **Approval Criteria**

**1** - Diagnosis of moderate to severe plaque psoriasis

**AND**

**2** - ONE of the following:

**2.1** ALL of the following:

**2.1.1** Greater than or equal to 3% body surface area involvement, palmoplantar, facial, or genital involvement, or severe scalp psoriasis

**AND**

**2.1.2** ONE of the following:

**2.1.2.1** Failure to ONE of the following topical therapy classes confirmed by claims history or submission of medical records:

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin
- Coal tar

**OR**

**2.1.2.2** History of intolerance or contraindication to ALL of the following topical therapy classes (please specify intolerance or contraindication):

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin
- Coal tar

**AND**

**2.1.3** ONE of the following:

**2.1.3.1** Failure to a 3 month trial of methotrexate at the maximally indicated dose confirmed by claims history or submission of medical records

**OR**

**2.1.3.2** History of intolerance or contraindication to methotrexate (please specify intolerance or contraindication)

**OR**

**2.2** Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of plaque psoriasis as confirmed by claims history or submission of medical records [e.g., Cimzia (certolizumab), adalimumab, Otezla (apremilast), Skyrizi (risankizumab-rzaa), ustekinumab, Tremfya (guselkumab)]

**AND**

**3** - ONE of the following:

**3.1** Patient is currently on Sotyktu therapy as confirmed by claims history or submission of medical records

**OR**

**3.2** BOTH of the following:

**3.2.1** ONE of the following:

**3.2.1.1** Failure to ALL of the following preferred products confirmed by claims history or submission of medical records:

- One of the preferred adalimumab products\*
- Enbrel (etanercept)
- One of the preferred ustekinumab products\*

**OR**

**3.2.1.2** History of intolerance or contraindication to ALL of the following preferred products (please specify intolerance or contraindication):

- One of the preferred adalimumab products\*
- Enbrel (etanercept)
- One of the preferred ustekinumab products\*

**AND**

**3.2.2** ONE of the following:

**3.2.2.1** Failure to Cosentyx (secukinumab) confirmed by claims history or submission of medical records

**OR**

**3.2.2.2** History of intolerance or contraindication to Cosentyx (secukinumab) (please specify intolerance or contraindication)

**AND**

**4** - Patient is NOT receiving Sotyktu in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

**AND**

**5** - Prescribed by or in consultation with a dermatologist

|       |                              |
|-------|------------------------------|
| Notes | *See PDL links in Background |
|-------|------------------------------|

|                      |                  |
|----------------------|------------------|
| Product Name:Sotyktu |                  |
| Diagnosis            | Plaque Psoriasis |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                     |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 12 month(s)         |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p>1 - Documentation of positive clinical response to Sotyktu therapy</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Patient is NOT receiving Sotyktu in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]</p> |                     |

## 2 . Background

| Benefit/Coverage/Program Information                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p><b>PDL Links</b></p> <p>CO: <a href="https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html</a></p> <p>HI: <a href="https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html</a></p> <p>MD: <a href="https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-cp-pharmacy.html</a></p> <p>NJ: <a href="https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html</a></p> |



NM: <https://www.uhcprovider.com/en/health-plans-by-state/new-mexico-health-plans/nm-comm-plan-home/nm-cp-pharmacy.html>

NY: <https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html>

PA: <https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP>

RI: <https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html>

### 3 . Revision History

| Date     | Notes                                                                                                                                                                                                                                                           |
|----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 3/4/2025 | Updated formularies. Removed reference to brand Stelara throughout. Removed Ilumya step in PsO section and added preferred ustekinumab as step therapy option. Added bypass language to patients currently taking Sotyktu. Added NM to PDL links in background. |

Spevigo



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-324200                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Guideline Name</b> | Spevigo                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Washington (ACUWA, ACUWAAHE, ACUWAC)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 8/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                         |                       |
|-------------------------|-----------------------|
| Product Name:Spevigo SC |                       |
| Approval Length         | 12 month(s)           |
| Therapy Stage           | Initial Authorization |
| Guideline Type          | Prior Authorization   |

**Approval Criteria**

**1** - Diagnosis of generalized pustular psoriasis (GPP) based on BOTH of the following:

**1.1** Presence of primary, sterile, macroscopically visible pustules on erythematous

**AND**

**1.2** Pustulation is NOT restricted to the acral region or within psoriatic plaques

**AND**

**2** - BOTH of the following:

- Used to prevent GPP flares
- Patient is NOT currently experiencing a GPP flare

**AND**

**3** - ONE of the following:

**3.1** Patient has been established on therapy with Spevigo for GPP under an active UnitedHealthcare medical benefit prior authorization

**OR**

**3.2** Patient is currently on Spevigo therapy for GPP as documented by claims history or submission of medical records

**AND**

**4** - Patient is NOT receiving Spevigo in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), ustekinumab, Skyrizi (risankizumab)] for treatment of the same indication

**AND**

**5** - Prescribed by a dermatologist

Product Name:Spevigo SC

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                 |
|---------------|-----------------|
| Therapy Stage | Reauthorization |
|---------------|-----------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

### Approval Criteria

**1** - Documentation of positive clinical response to therapy [e.g., preventing flares, reducing frequency of flares, prolonging time between flares, controlling signs and symptoms of GPP (e.g. pustules, erythema, pain, itching) between flares]

**AND**

**2** - Reduction in the utilization of therapy (e.g., intravenous Spevigo) used for GPP flares

**AND**

**3** - Patient is NOT receiving Spevigo in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), ustekinumab, Skyrizi (risankizumab)] for treatment of the same indication

**AND**

**4** - Prescribed by a dermatologist

## 2 . Revision History

UnitedHealthcare Community Plan of New Jersey – Clinical Pharmacy Guidelines

| Date      | Notes                                                                                                                                                                    |
|-----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 7/10/2025 | Revised diagnostic criteria per consensus guidelines. Updated combination use language. Removed date and duration requirement for patients currently on Spevigo therapy. |

Spravato



## Prior Authorization Guideline

|                       |                                                                                                         |
|-----------------------|---------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-235236                                                                                               |
| <b>Guideline Name</b> | Spravato                                                                                                |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>Medicaid - Community &amp; State New Jersey (PSI2300)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 6/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                                                                                                                                                                                                                                                   |                                                 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|
| Product Name:Spravato*                                                                                                                                                                                                                            |                                                 |
| Diagnosis                                                                                                                                                                                                                                         | Major Depressive Disorder (Treatment-Resistant) |
| Approval Length                                                                                                                                                                                                                                   | 12 month(s)                                     |
| Therapy Stage                                                                                                                                                                                                                                     | Initial Authorization                           |
| Guideline Type                                                                                                                                                                                                                                    | Prior Authorization                             |
| <b>Approval Criteria</b><br><br>1 - Diagnosis of major depressive disorder (treatment-resistant), according to the current Diagnostic and Statistical Manual of Mental Disorders (DSM) (i.e., DSM-5-TR) criteria, by a mental health professional |                                                 |

**AND**

**2** - Submission of medical records (e.g., chart notes, laboratory values) documenting baseline scoring (prior to starting Spravato) on at least ONE of the following clinical assessments has been completed:<sup>^</sup>

- Beck Depression Inventory (BDI)
- Hamilton Rating Scale for Depression (HAM-D)
- Montgomery-Asberg Depression Rating Scale (MADRS)
- 9-item Patient Health Questionnaire (PHQ-9)
- Quick Inventory of Depressive Symptomatology (QIDS)

**AND**

**3** - History of failure of a trial of at least TWO different antidepressant medications or treatment regimens for a duration of at least 3 weeks each, confirmed by claims history or submitted medical records. An antidepressant or treatment regimen would include any of the following classes or combinations:<sup>^</sup>

- Selective serotonin reuptake inhibitors (e.g., citalopram, fluoxetine, paroxetine, sertraline)
- Serotonin norepinephrine reuptake inhibitors (e.g., duloxetine, venlafaxine, etc.)
- Bupropion
- Tricyclic antidepressants (e.g., amitriptyline, clomipramine, nortriptyline, etc.)
- Mirtazapine
- Monoamine oxidase inhibitors (e.g., selegiline, tranylcypromine, etc.)
- Serotonin modulators (e.g., nefazodone, trazodone, etc.)
- Augmentation with antipsychotics, lithium, or thyroid hormone

**AND**

**4** - Provider and/or the provider's healthcare setting is certified in the Spravato REMS (Risk Evaluation and Mitigation Strategy) program

|       |                                                                                                                                                                                                                                                                                                                                                                            |
|-------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Notes | *Please reference the current NJ PDL: <a href="https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html</a> ^NJ Psych Panel (any mental health prescriber) is not subject to this criterion. |
|-------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                                     |                                                 |
|-------------------------------------|-------------------------------------------------|
| Product Name: Spravato <sup>^</sup> |                                                 |
| Diagnosis                           | Major Depressive Disorder (Treatment-Resistant) |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                             |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 12 month(s)                                                                                                                                                 |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Reauthorization                                                                                                                                             |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Prior Authorization                                                                                                                                         |
| <p><b>Approval Criteria</b></p> <p>1 - Documentation of remission or a positive clinical response to Spravato therapy</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Submission of medical records (e.g., chart notes, laboratory values) documenting baseline and recent (within the last month) scoring on at least ONE of the following assessments demonstrating remission or clinical response (e.g., score reduction from baseline):</p> <ul style="list-style-type: none"> <li>• Beck Depression Inventory (BDI)</li> <li>• Hamilton Rating Scale for Depression (HAM-D)</li> <li>• Montgomery-Asberg Depression Rating Scale (MADRS)</li> <li>• 9-item Patient Health Questionnaire (PHQ-9)</li> <li>• Quick Inventory of Depressive Symptomatology (QIDS)</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p>3 - Provider and/or the provider's healthcare setting is certified in the Spravato REMS (Risk Evaluation and Mitigation Strategy) program</p> |                                                                                                                                                             |
| Notes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | ^NJ Psych Panel Providers (any mental health prescriber) would override non-preferred status and are only subject to initial authorization diagnosis check. |

|                                 |                                                                                                               |
|---------------------------------|---------------------------------------------------------------------------------------------------------------|
| Product Name: Spravato*         |                                                                                                               |
| Diagnosis                       | Depressive symptoms in an adult with major depressive disorder (MDD) with acute suicidal ideation or behavior |
| Approval Length                 | 12 month(s)                                                                                                   |
| Guideline Type                  | Prior Authorization                                                                                           |
| <p><b>Approval Criteria</b></p> |                                                                                                               |



**1** - Diagnosis of major depressive disorder according to the current Diagnostic and Statistical Manual of Mental Disorders (DSM) (i.e., DSM-5-TR) criteria, by a mental health professional

**AND**

**2** - Patient is experiencing an acute suicidal ideation or behavior^

**AND**

**3** - Spravato will be used in combination with a newly initiated or optimized oral antidepressant^

**AND**

**4** - Provider and/or the provider's healthcare setting is certified in the Spravato REMS (Risk Evaluation and Mitigation Strategy) program

|       |                                                                                                                                                                                                                                                                                                                                 |
|-------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Notes | <p>*Spravato is hard-coded with a quantity of 0.29 per day for the 56mg strength and 0.43 per day for the 84mg strength. If criteria are met, enter one GPI-12 authorization with an MDD override of 1 and a PQE of 24 per 28 days.</p> <p>^NJ Psych Panel (any mental health prescriber) is not subject to this criterion.</p> |
|-------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                 |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Product Name: Spravato*                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                                 |
| Diagnosis                                                                                                                                                                                                               | Depressive symptoms in an adult with major depressive disorder (MDD) with acute suicidal ideation or behavior                                                                                                                                                                                                                   |
| Approval Length                                                                                                                                                                                                         | 12 month(s)                                                                                                                                                                                                                                                                                                                     |
| Guideline Type                                                                                                                                                                                                          | Quantity Limit                                                                                                                                                                                                                                                                                                                  |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - The requested drug is prescribed within the manufacturer's published dosing guidelines or falls within dosing guidelines found in the compendia of current literature</p> |                                                                                                                                                                                                                                                                                                                                 |
| Notes                                                                                                                                                                                                                   | <p>*Spravato is hard-coded with a quantity of 0.29 per day for the 56mg strength and 0.43 per day for the 84mg strength. If criteria are met, enter one GPI-12 authorization with an MDD override of 1 and a PQE of 24 per 28 days.</p> <p>^NJ Psych Panel (any mental health prescriber) is not subject to this criterion.</p> |

|  |                                                                                    |
|--|------------------------------------------------------------------------------------|
|  | er one GPI-12 authorization with an MDD override of 1 and a PQE of 24 per 28 days. |
|--|------------------------------------------------------------------------------------|

## 2 . Revision History

| Date     | Notes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 4/9/2025 | Revised options for clinical assessments to reflect different item versions of the same scale as well as added BDI. Removed requirement for combination with oral antidepressant for TRD per updated label. Revised coverage criteria for TRD to require history of failure of a trial of at least two different antidepressant medications or treatment regimens, removed reference to current depressive episode, and removed augmentation with anticonvulsants as a treatment regimen based on latest clinical evidence. |

Sprycel



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-161079                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Guideline Name</b> | Sprycel                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 1/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                                                |                                                                                |
|------------------------------------------------|--------------------------------------------------------------------------------|
| Product Name: Brand Sprycel, generic dasatinib |                                                                                |
| Diagnosis                                      | Philadelphia Chromosome-Positive or BCR-ABL1-Positive Chronic Myeloid Leukemia |
| Approval Length                                | 12 month(s)                                                                    |
| Therapy Stage                                  | Initial Authorization                                                          |
| Guideline Type                                 | Prior Authorization                                                            |

**Approval Criteria**

**1** - Diagnosis of Philadelphia chromosome-positive or BCR-ABL1-positive chronic myeloid leukemia

**AND**

**2** - ONE of the following:

**2.1** Patient is not a candidate for imatinib as attested by physician

**OR**

**2.2** Patient is currently on Sprycel therapy

|                                                                                                                                       |                                                                        |
|---------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------|
| Product Name:Brand Sprycel, generic dasatinib                                                                                         |                                                                        |
| Diagnosis                                                                                                                             | Philadelphia Chromosome-Positive Acute Lymphoblastic Leukemia (Ph+ALL) |
| Approval Length                                                                                                                       | 12 month(s)                                                            |
| Therapy Stage                                                                                                                         | Initial Authorization                                                  |
| Guideline Type                                                                                                                        | Prior Authorization                                                    |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ALL)</p> |                                                                        |

|                                               |                                       |
|-----------------------------------------------|---------------------------------------|
| Product Name:Brand Sprycel, generic dasatinib |                                       |
| Diagnosis                                     | Gastrointestinal Stromal Tumor (GIST) |
| Approval Length                               | 12 month(s)                           |
| Therapy Stage                                 | Initial Authorization                 |
| Guideline Type                                | Prior Authorization                   |

**Approval Criteria**

1 - Diagnosis of gastrointestinal stromal tumor (GIST) with PDGFRA exon 18 mutations

Product Name: Brand Sprycel, generic dasatinib

|           |                |
|-----------|----------------|
| Diagnosis | Chondrosarcoma |
|-----------|----------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

1 - Diagnosis of metastatic chondrosarcoma

Product Name: Brand Sprycel, generic dasatinib

|           |          |
|-----------|----------|
| Diagnosis | Chordoma |
|-----------|----------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

1 - Diagnosis of recurrent chordoma

Product Name: Brand Sprycel, generic dasatinib

|           |                                              |
|-----------|----------------------------------------------|
| Diagnosis | Myeloid/Lymphoid Neoplasms with Eosinophilia |
|-----------|----------------------------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

**1** - Diagnosis of lymphoid, myeloid, or mixed lineage neoplasms with eosinophilia

**AND**

**2** - Patient has an ABL1 (gene) rearrangement

Product Name: Brand Sprycel, generic dasatinib

|           |                    |
|-----------|--------------------|
| Diagnosis | Cutaneous Melanoma |
|-----------|--------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

**1** - Diagnosis of cutaneous melanoma

**AND**

**2** - Tumors are metastatic or unresectable

**AND**

**3** - Contains activating mutations of KIT

**AND**

**4** - Used as second-line or subsequent therapy for disease progression, intolerance, and/or projected risk of progression with BRAF-targeted therapy

| Product Name:Brand Sprycel, generic dasatinib                                                                      |                                                                                                                                                                                          |
|--------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Diagnosis                                                                                                          | Philadelphia Chromosome-Positive or BCR-ABL1-Positive Chronic Myeloid Leukemia, Ph+ALL, GIST, Chondrosarcoma, Chordoma, Myeloid/Lymphoid Neoplasms with Eosinophilia, Cutaneous Melanoma |
| Approval Length                                                                                                    | 12 month(s)                                                                                                                                                                              |
| Therapy Stage                                                                                                      | Reauthorization                                                                                                                                                                          |
| Guideline Type                                                                                                     | Prior Authorization                                                                                                                                                                      |
| <b>Approval Criteria</b><br><br>1 - Patient does not show evidence of progressive disease while on Sprycel therapy |                                                                                                                                                                                          |

| Product Name:Brand Sprycel, generic dasatinib                                                                                           |                           |
|-----------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Diagnosis                                                                                                                               | NCCN Recommended Regimens |
| Approval Length                                                                                                                         | 12 month(s)               |
| Therapy Stage                                                                                                                           | Initial Authorization     |
| Guideline Type                                                                                                                          | Prior Authorization       |
| <b>Approval Criteria</b><br><br>1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium |                           |

| Product Name:Brand Sprycel, generic dasatinib |                           |
|-----------------------------------------------|---------------------------|
| Diagnosis                                     | NCCN Recommended Regimens |
| Approval Length                               | 12 month(s)               |
| Therapy Stage                                 | Reauthorization           |
| Guideline Type                                | Prior Authorization       |
| <b>Approval Criteria</b>                      |                           |

1 - Documentation of positive clinical response to Sprycel therapy

## 2 . Revision History

| Date       | Notes                                                                    |
|------------|--------------------------------------------------------------------------|
| 11/20/2024 | Updated GPIs and product list to add generic. Updated criteria for GI ST |



Stivarga



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-370210                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Guideline Name</b> | Stivarga                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 9/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                       |                         |
|-----------------------|-------------------------|
| Product Name:Stivarga |                         |
| Diagnosis             | Colorectal Cancer (CRC) |
| Approval Length       | 12 month(s)             |
| Therapy Stage         | Initial Authorization   |

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Prior Authorization |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of advanced or metastatic colorectal cancer</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - History of failure, contraindication, or intolerance to treatment with ALL of the following:</p> <ul style="list-style-type: none"> <li>• Oxaliplatin-based chemotherapy</li> <li>• Irinotecan-based chemotherapy</li> <li>• Anti-VEGF based chemotherapy</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - ONE of the following:</p> <p><b>3.1</b> Tumor is RAS mutant-type</p> <p style="text-align: center;"><b>OR</b></p> <p><b>3.2</b> BOTH of the following:</p> <ul style="list-style-type: none"> <li>• Tumor is RAS wild-type</li> <li>• History of failure, contraindication, or intolerance to anti-EGFR therapy [e.g., Erbitux (cetuximab), Vectibix (panitumumab)]</li> </ul> |                     |

|                       |                           |
|-----------------------|---------------------------|
| Product Name:Stivarga |                           |
| Diagnosis             | Soft Tissue Sarcoma (STS) |
| Approval Length       | 12 month(s)               |
| Therapy Stage         | Initial Authorization     |
| Guideline Type        | Prior Authorization       |

**Approval Criteria**

1 - Diagnosis of soft tissue sarcoma (STS)

**AND**

2 - ONE of the following:

**2.1** Extremity/superficial trunk or head/neck that is non-adipocytic with advanced/metastatic disease with disseminated metastases

**OR**

**2.2** Retroperitoneal/intra-abdominal that is non-adipocytic with recurrent unresectable or stage IV disease

**OR**

**2.3** Advanced/metastatic pleomorphic rhabdomyosarcoma

**OR**

**2.4** Angiosarcoma

|                          |                                       |
|--------------------------|---------------------------------------|
| Product Name:Stivarga    |                                       |
| Diagnosis                | Gastrointestinal Stromal Tumor (GIST) |
| Approval Length          | 12 month(s)                           |
| Therapy Stage            | Initial Authorization                 |
| Guideline Type           | Prior Authorization                   |
| <b>Approval Criteria</b> |                                       |

**1 - Diagnosis of gastrointestinal stromal tumor (GIST)**

**AND**

**2 - Disease is one of the following:**

- Gross residual (R2 resection)
- Unresectable primary
- Tumor rupture
- Recurrent/metastatic

**AND**

**3 - One of the following:**

**3.1 SDH-deficient GIST**

**OR**

**3.2 History of disease progression on BOTH of the following as confirmed by claims history or submission of medical records:**

**3.2.1 Imatinib mesylate (generic Gleevec)**

**AND**

**3.2.2 One of the following:**

- sunitinib malate (generic Sutent)
- Qinlock (ripretinib)

|                       |                       |
|-----------------------|-----------------------|
| Product Name:Stivarga |                       |
| Diagnosis             | Hepatobiliary Cancers |
| Approval Length       | 12 month(s)           |
| Therapy Stage         | Initial Authorization |

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Prior Authorization |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1 - Both of the following:</b></p> <p><b>1.1</b> Diagnosis of ONE of the following:</p> <ul style="list-style-type: none"> <li>• Gallbladder cancer</li> <li>• Extrahepatic cholangiocarcinoma</li> <li>• Intrahepatic cholangiocarcinoma</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>1.2</b> Disease is ONE of the following:</p> <ul style="list-style-type: none"> <li>• Unresectable</li> <li>• Gross residual (R2)</li> <li>• Metastatic</li> </ul> <p style="text-align: center;"><b>OR</b></p> <p><b>2 - BOTH of the following:</b></p> <p><b>2.1</b> Diagnosis of hepatocellular carcinoma</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2.2</b> Used as subsequent-line therapy for disease progression</p> |                     |

|                       |                       |
|-----------------------|-----------------------|
| Product Name:Stivarga |                       |
| Diagnosis             | Bone Cancer           |
| Approval Length       | 12 month(s)           |
| Therapy Stage         | Initial Authorization |
| Guideline Type        | Prior Authorization   |

### Approval Criteria

1 - Diagnosis of ONE of the following bone cancers:

- Dedifferentiated chondrosarcoma
- Ewing Sarcoma
- High grade undifferentiated pleomorphic sarcoma (UPS)
- Mesenchymal chondrosarcoma
- Osteosarcoma
- Other primary round cell tumors of the bone (e.g., CIC::DUX4, BCOR::CCNB3)

**AND**

2 - Used as second-line therapy

|                                                                                    |                       |
|------------------------------------------------------------------------------------|-----------------------|
| Product Name:Stivarga                                                              |                       |
| Diagnosis                                                                          | Glioblastoma          |
| Approval Length                                                                    | 12 month(s)           |
| Therapy Stage                                                                      | Initial Authorization |
| Guideline Type                                                                     | Prior Authorization   |
| <b>Approval Criteria</b><br>1 - Diagnosis of recurrent or progressive glioblastoma |                       |

|                       |                       |
|-----------------------|-----------------------|
| Product Name:Stivarga |                       |
| Diagnosis             | Uterine Sarcoma       |
| Approval Length       | 12 month(s)           |
| Therapy Stage         | Initial Authorization |
| Guideline Type        | Prior Authorization   |
|                       |                       |

**Approval Criteria**

**1** - Diagnosis of uterine sarcoma

**AND**

**2** - Disease is one of the following:

- Advanced
- Recurrent/metastatic
- Inoperable

**AND**

**3** - Used as second-line or subsequent therapy

| Product Name:Stivarga                                                                                                             |                                                                                                                                                             |
|-----------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Diagnosis                                                                                                                         | Colorectal Cancer (CRC), Soft Tissue Sarcoma (STS), Gastrointestinal Stromal Tumor (GIST), Hepatobiliary Cancer, Bone Cancer, Glioblastoma, Uterine Sarcoma |
| Approval Length                                                                                                                   | 12 month(s)                                                                                                                                                 |
| Therapy Stage                                                                                                                     | Reauthorization                                                                                                                                             |
| Guideline Type                                                                                                                    | Prior Authorization                                                                                                                                         |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Patient does not show evidence of progressive disease while on Stivarga therapy</p> |                                                                                                                                                             |

| Product Name:Stivarga |                           |
|-----------------------|---------------------------|
| Diagnosis             | NCCN Recommended Regimens |
| Approval Length       | 12 month(s)               |
| Therapy Stage         | Initial Authorization     |
| Guideline Type        | Prior Authorization       |

**Approval Criteria**

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

|                                                                                                            |                           |
|------------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Stivarga                                                                                      |                           |
| Diagnosis                                                                                                  | NCCN Recommended Regimens |
| Approval Length                                                                                            | 12 month(s)               |
| Therapy Stage                                                                                              | Reauthorization           |
| Guideline Type                                                                                             | Prior Authorization       |
| <p><b>Approval Criteria</b></p> <p>1 - Documentation of positive clinical response to Stivarga therapy</p> |                           |

## 2 . Revision History

| Date      | Notes                                                                             |
|-----------|-----------------------------------------------------------------------------------|
| 8/15/2025 | Combined formularies. Added criteria for uterine sarcoma. Other criteria updates. |



Strensiq



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-136412                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Guideline Name</b> | Strensiq                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 1/1/2024 |
|-----------------|----------|

## 1 . Criteria

|                       |                       |
|-----------------------|-----------------------|
| Product Name:Strensiq |                       |
| Approval Length       | 6 month(s)            |
| Therapy Stage         | Initial Authorization |
| Guideline Type        | Prior Authorization   |
|                       |                       |

## **Approval Criteria**

**1** - Diagnosis of perinatal/infantile or juvenile-onset hypophosphatasia based on ALL of the following:

**1.1** ONE of the following:

**1.1.1** Onset of clinical signs and symptoms of hypophosphatasia prior to age 18 years (e.g., respiratory insufficiency, vitamin B6 responsive seizures, hypotonia, failure to thrive, delayed walking, waddling gait, dental abnormalities, low trauma fractures)

**OR**

**1.1.2** Radiographic evidence supporting the diagnosis of hypophosphatasia at the age of onset prior to age 18 years (e.g., craniosynostosis, infantile rickets, non-traumatic fractures)

**AND**

**1.2** ONE of the following:

**1.2.1** BOTH of the following:

**1.2.1.1** Patient has low level activity of serum alkaline phosphatase (ALP) evidenced by an ALP level below the age and gender-adjusted normal range

**AND**

**1.2.1.2** Patient has an elevated level of tissue non-specific alkaline phosphatase (TNSALP) substrate [e.g., serum pyridoxal 5'-phosphate (PLP) level, serum or urine phosphoethanolamine (PEA) level, urinary inorganic pyrophosphate (PPi level)]

**OR**

**1.2.2** Confirmation of tissue-nonspecific alkaline phosphatase (TNSALP) gene mutation by ALPL genomic DNA (deoxyribonucleic acid) testing\*

**AND**

**2** - Prescribed by ONE of the following:

- Endocrinologist
- A specialist experienced in the treatment of metabolic bone disorders

**AND**

**3 - ONE of the following:**

**3.1 BOTH of the following:**

**3.1.1** Diagnosis of perinatal/infantile-onset hypophosphatasia

**AND**

**3.1.2** Request does not exceed a maximum supply limit of 9 mg/kg/week (milligrams/kilogram/week)

**OR**

**3.2 BOTH of the following:**

**3.2.1** Diagnosis of juvenile-onset hypophosphatasia

**AND**

**3.2.2** Request does not exceed a maximum supply limit of 6 mg/kg/week

**AND**

**4 - ONE of the following:**

**4.1** Patient is prescribed Strensiq 18 mg/0.45 mL (milliliter), Strensiq 28 mg/0.7 mL, or Strensiq 40 mg/mL vials

**OR**

**4.2 BOTH of the following:**

**4.2.1** Patient is prescribed Strensiq 80 mg/0.8 mL vial

**AND**

**4.2.2** Patient's weight is greater than or equal to 40 kg

|       |                                                                                                                                                                                                                                                       |
|-------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Notes | *Results of prior genetic testing can be submitted as confirmation of diagnosis of HPP, however please note that the provider should confirm coverage status of any new genetic testing under the patient's United Healthcare plan prior to ordering. |
|-------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                     |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Strensiq                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                     |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | 12 month(s)         |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of positive clinical response to Strensiq therapy (e.g., improvement in clinical symptoms, improvement in Radiographic Global Impression of Change)</p> <p><b>AND</b></p> <p><b>2</b> - Clinically relevant decrease from baseline in tissue non-specific alkaline phosphatase (TNSALP) substrate [e.g., serum pyridoxal 5'-phosphate (PLP) level, serum or urine phosphoethanolamine (PEA) level, urinary inorganic pyrophosphate (PPi level)]</p> <p><b>AND</b></p> <p><b>3</b> - Prescribed by ONE of the following:</p> <ul style="list-style-type: none"> <li>• Endocrinologist</li> <li>• A specialist experienced in the treatment of metabolic bone diseases</li> </ul> <p><b>AND</b></p> |                     |

**4 - ONE of the following:**

**4.1 BOTH of the following:**

**4.1.1** Diagnosis of perinatal/infantile-onset hypophosphatasia

**AND**

**4.1.2** Request does not exceed a maximum supply limit of 9 mg/kg/week (milligrams/kilogram/week)

**OR**

**4.2 BOTH of the following:**

**4.2.1** Diagnosis of juvenile-onset hypophosphatasia

**AND**

**4.2.2** Request does not exceed a maximum supply limit of 6 mg/kg/week

**AND**

**5 - ONE of the following:**

**5.1** Patient is prescribed Strensiq 18 mg/0.45 mL (milliliter), Strensiq 28 mg/0.7 mL, or Strensiq 40 mg/mL vials

**OR**

**5.2 BOTH of the following:**

**5.2.1** Patient is prescribed Strensiq 80 mg/0.8 mL vials

**AND**

**5.2.2** Patient's weight is greater than or equal to 40 kg

## 2 . Revision History

| Date       | Notes                             |
|------------|-----------------------------------|
| 11/16/2023 | removal of routine audit language |

Stromectol



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-273208                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Guideline Name</b> | Stromectol                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Washington (ACUWA, ACUWAAHE, ACUWAC)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Pennsylvania (ACUPA)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 7/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                                                         |            |
|---------------------------------------------------------|------------|
| Product Name: Brand Stromectol, generic ivermectin tabs |            |
| Approval Length                                         | 1 month(s) |

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Prior Authorization |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1 - Diagnosis of ONE of the following:</b></p> <ul style="list-style-type: none"> <li>• Onchocerciasis due to nematode parasite</li> <li>• Pediculosis</li> <li>• Strongyloidiasis</li> <li>• Ascariasis</li> <li>• Scabies (including crusted scabies)</li> <li>• Cutaneous larva migrans (hook worm disease)</li> <li>• Enterobiasis</li> <li>• Filariasis</li> <li>• Trichuriasis</li> <li>• Gnathostomiasis</li> </ul> |                     |

## 2 . Revision History

| Date      | Notes                       |
|-----------|-----------------------------|
| 5/21/2025 | Updated GPIs to add 6mg tab |



Sublingual Immunotherapy (SLIT)



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-242230                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Guideline Name</b> | Sublingual Immunotherapy (SLIT)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Pennsylvania (ACUPA)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 6/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                      |                       |
|----------------------|-----------------------|
| Product Name:Grastek |                       |
| Approval Length      | 12 month(s)           |
| Therapy Stage        | Initial Authorization |
| Guideline Type       | Prior Authorization   |

### **Approval Criteria**

**1** - Diagnosis of moderate to severe grass pollen-induced allergic rhinitis defined by symptoms severe enough to interfere with quality of life (e.g., sleep disturbances; impairment of daily, sport, or leisure activities; impairment of school or work performance)

**AND**

**2** - Diagnosis confirmed by ONE of the following:

**2.1** Positive skin test to Timothy grass or cross-reactive grass pollens (e.g., Sweet Vernal, Orchard/Cocksfoot, Perennial Rye, Kentucky blue/June grass, Meadow Fescue, or Redtop)

**OR**

**2.2** In vitro testing for pollen-specific IgE (immunoglobulin E) antibodies for Timothy grass or cross-reactive grass pollens (e.g., Sweet Vernal, Orchard/Cocksfoot, Perennial Rye, Kentucky blue/June grass, Meadow Fescue, or Redtop)

**AND**

**3** - Treatment is started or will be started at least 12 weeks before the beginning of the grass pollen season

**AND**

**4** - ONE of the following:

**4.1** Failure to TWO of the following as confirmed by claims history or submission of medical records:

- oral antihistamine [e.g., cetirizine (Zyrtec)]
- intranasal antihistamine [e.g., azelastine (Astelin)]
- intranasal corticosteroid [e.g., fluticasone (Flonase)]
- leukotriene inhibitor [e.g., montelukast (Singulair)]

**OR**

**4.2** History of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):

- oral antihistamine [e.g., cetirizine (Zyrtec)]
- intranasal antihistamine [e.g., azelastine (Astelin)]
- intranasal corticosteroid [e.g., fluticasone (Flonase)]
- leukotriene inhibitor [e.g., montelukast (Singulair)]

**AND**

**5** - Not received in combination with similar cross-reactive grass pollen immunotherapy (e.g., Oralair)

**AND**

**6** - Patient does not have unstable and/or uncontrolled asthma

**AND**

**7** - Prescribed by or in consultation with a specialist in allergy and immunology

Product Name:Grastek

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                 |
|---------------|-----------------|
| Therapy Stage | Reauthorization |
|---------------|-----------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

**1** - Documentation of positive clinical response to Grastek therapy

Product Name:Oralair

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                       |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of moderate to severe grass pollen-induced allergic rhinitis defined by symptoms severe enough to interfere with quality of life (e.g., sleep disturbances; impairment of daily, sport, or leisure activities; impairment of school or work performance)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Diagnosis confirmed by ONE of the following:</p> <p><b>2.1</b> Positive skin test to any of the five grass species contained in Oralair [(i.e., Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue grass mixed pollens) or cross-reactive grass pollens (e.g., Cocksfoot, Meadow Fescue, or Redtop)]</p> <p style="text-align: center;"><b>OR</b></p> <p><b>2.2</b> In vitro testing for pollen-specific IgE (immunoglobulin E) antibodies for any of the five grass species contained in Oralair [(i.e., Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue grass mixed pollens) or cross-reactive grass pollens (e.g., Cocksfoot, Meadow Fescue, or Redtop)]</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Treatment is started or will be started at least 4 months before the beginning of the grass pollen season</p> <p style="text-align: center;"><b>AND</b></p> <p><b>4</b> - ONE of the following:</p> <p><b>4.1</b> Failure to TWO of the following as confirmed by claims history or submission of medical records:</p> |                       |

- oral antihistamine [e.g., cetirizine (Zyrtec)]
- intranasal antihistamine [e.g., azelastine (Astelin)]
- intranasal corticosteroid [e.g., fluticasone (Flonase)]
- leukotriene inhibitor [e.g., montelukast (Singulair)]

**OR**

**4.2** History of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):

- oral antihistamine [e.g., cetirizine (Zyrtec)]
- intranasal antihistamine [e.g., azelastine (Astelin)]
- intranasal corticosteroid [e.g., fluticasone (Flonase)]
- leukotriene inhibitor [e.g., montelukast (Singulair)]

**AND**

**5** - Not received in combination with similar cross-reactive grass pollen immunotherapy (e.g., Grastek)

**AND**

**6** - Patient does not have unstable and/or uncontrolled asthma

**AND**

**7** - Prescribed by or in consultation with a specialist in allergy and immunology

|                       |                     |
|-----------------------|---------------------|
| Product Name: Oralair |                     |
| Approval Length       | 12 month(s)         |
| Therapy Stage         | Reauthorization     |
| Guideline Type        | Prior Authorization |
| Approval Criteria     |                     |

**1 - Documentation of positive clinical response to Oralair therapy**

|                              |                       |
|------------------------------|-----------------------|
| <b>Product Name:Ragwitek</b> |                       |
| Approval Length              | 12 month(s)           |
| Therapy Stage                | Initial Authorization |
| Guideline Type               | Prior Authorization   |

**Approval Criteria**

**1 - Diagnosis of moderate to severe short ragweed pollen-induced allergic rhinitis defined by symptoms severe enough to interfere with quality of life (e.g., sleep disturbances; impairment of daily, sport, or leisure activities; impairment of school or work performance)**

**AND**

**2 - Diagnosis confirmed by ONE of the following:**

- Positive skin test to short ragweed pollen
- In vitro testing for pollen-specific IgE (immunoglobulin E) antibodies for short ragweed pollen

**AND**

**3 - Treatment is started or will be started at least 12 weeks before the beginning of the short ragweed pollen season**

**AND**

**4 - ONE of the following:**

**4.1 Failure to TWO of the following as confirmed by claims history or submission of medical records:**

- oral antihistamine [e.g., cetirizine (Zyrtec)]
- intranasal antihistamine [e.g., azelastine (Astelin)]
- intranasal corticosteroid [e.g., fluticasone (Flonase)]

- leukotriene inhibitor [e.g., montelukast (Singulair)]

**OR**

**4.2** History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication):

- oral antihistamine [e.g., cetirizine (Zyrtec)]
- intranasal antihistamine [e.g., azelastine (Astelin)]
- intranasal corticosteroid [e.g., fluticasone (Flonase)]
- leukotriene inhibitor [e.g., montelukast (Singulair)]

**AND**

**5** - Patient does not have unstable and/or uncontrolled asthma

**AND**

**6** - Prescribed by or in consultation with a specialist in allergy and immunology

|                                                                                                        |                     |
|--------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Ragwitek                                                                                  |                     |
| Approval Length                                                                                        | 12 month(s)         |
| Therapy Stage                                                                                          | Reauthorization     |
| Guideline Type                                                                                         | Prior Authorization |
| <b>Approval Criteria</b><br><b>1</b> - Documentation of positive clinical response to Ragwitek therapy |                     |

|                      |                       |
|----------------------|-----------------------|
| Product Name:Odactra |                       |
| Approval Length      | 12 month(s)           |
| Therapy Stage        | Initial Authorization |
| Guideline Type       | Prior Authorization   |

## **Approval Criteria**

**1** - Diagnosis of house dust mite (HDM)-induced allergic rhinitis

**AND**

**2** - Diagnosis confirmed by ONE of the following:

- Positive skin test to licensed house dust mite allergen extracts
- In vitro testing for IgE (immunoglobulin E) antibodies to *Dermatophagoides farinae* or *Dermatophagoides pteronyssinus* house dust mites

**AND**

**3** - ONE of the following:

**3.1** Failure to TWO of the following as confirmed by claims history or submission of medical records:

- oral antihistamine [e.g., cetirizine (Zyrtec)]
- intranasal antihistamine [e.g., azelastine (Astelin)]
- intranasal corticosteroid [e.g., fluticasone (Flonase)]
- leukotriene inhibitor [e.g., montelukast (Singulair)]

**OR**

**3.2** History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication):

- oral antihistamine [e.g., cetirizine (Zyrtec)]
- intranasal antihistamine [e.g., azelastine (Astelin)]
- intranasal corticosteroid [e.g., fluticasone (Flonase)]
- leukotriene inhibitor [e.g., montelukast (Singulair)]

**AND**

**4** - Patient does not have unstable and/or uncontrolled asthma



**AND**

**5** - Prescribed by or in consultation with a specialist in allergy and immunology

Product Name:Odactra

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                 |
|---------------|-----------------|
| Therapy Stage | Reauthorization |
|---------------|-----------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

**1** - Documentation of positive clinical response to Odactra therapy

## 2 . Revision History

| Date | Notes |
|------|-------|
|------|-------|

|           |                      |
|-----------|----------------------|
| 4/18/2025 | Combined formularies |
|-----------|----------------------|

Sucraid



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-206584                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Guideline Name</b> | Sucraid                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 4/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                       |                       |
|-----------------------|-----------------------|
| Product Name: Sucraid |                       |
| Approval Length       | 3 month(s)            |
| Therapy Stage         | Initial Authorization |

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Prior Authorization |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Submission of medical records documenting a diagnosis of congenital sucrase-isomaltase deficiency (CSID)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Submission of medical records documenting diagnosis has been confirmed by one of the following:</p> <p><b>2.1</b> Endoscopic biopsy of the small bowel indicating ALL of the following:</p> <p><b>2.1.1</b> Normal small bowel morphology</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2.1.2</b> Absent or markedly reduced sucrase activity</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2.1.3</b> Isomaltase activity varying from 0 to full activity</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2.1.4</b> Reduced maltase activity</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2.1.5</b> ONE of the following:</p> <p><b>2.1.5.1</b> Normal lactase activity</p> |                     |

**OR**

**2.1.5.2** BOTH of the following:

- Reduced lactase
- Sucrase:lactase ratio of less than 1.0

**OR**

**2.2** Molecular genetic testing of the sucrase-isomaltase (SI) gene indicating a pathogenic isomaltase gene variant

**OR**

**2.3** Carbon-13 sucrose breath test (13C SBT) indicating a cumulative [13C] CO<sub>2</sub> exhalation over 90 minutes below 10th percentile (i.e., less than 3.9% for men and less than 5.2% for women)

**AND**

**3** - Prescribed by or in consultation with a gastroenterologist or rare disease specialist

**AND**

**4** - Will be used with a sucrose-free, low starch diet

|                       |                     |
|-----------------------|---------------------|
| Product Name: Sucraid |                     |
| Approval Length       | 12 month(s)         |
| Therapy Stage         | Reauthorization     |
| Guideline Type        | Prior Authorization |
| Approval Criteria     |                     |

**1** - Documentation of positive clinical response to Sucraid therapy [e.g., reduced symptoms (e.g., abdominal pain, bloating, gas, vomiting), reduced number of stools per day, reduced number of symptomatic days]

**AND**

**2** - Prescribed by or in consultation with a gastroenterologist or rare disease specialist

**AND**

**3** - Will be used with a sucrose-free, low starch diet

## 2 . Revision History

| Date     | Notes                                                                                                                        |
|----------|------------------------------------------------------------------------------------------------------------------------------|
| 3/5/2025 | Updated formularies. Added requirement for submission of medical records documenting diagnosis and confirmation of diagnosis |

Sunosi



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-451199                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Guideline Name</b> | Sunosi                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 12/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                     |                       |
|---------------------|-----------------------|
| Product Name:Sunosi |                       |
| Diagnosis           | Narcolepsy            |
| Approval Length     | 12 month(s)           |
| Therapy Stage       | Initial Authorization |
| Guideline Type      | Prior Authorization   |

## **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes, lab values) documenting a diagnosis of narcolepsy with BOTH of the following:

**1.1** The patient has daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least three months.

**AND**

**1.2** A mean sleep latency of less than or equal to 8 minutes and two or more sleep onset rapid eye movement (REM) periods (SOREMPs) are found on a multiple sleep latency test (MSLT) performed according to standard techniques following a normal overnight polysomnogram. A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal polysomnogram may replace one of the SOREMPs on the MSLT.

**AND**

**2** - Physician attestation that other causes of sleepiness have been ruled out or treated (including but not limited to obstructive sleep apnea, insufficient sleep syndrome, shift work, the effects of substances or medications or their withdrawal, sleep phase disorder, or other sleep disorders)

**AND**

**3** - ONE of the following:

**3.1** Failure to BOTH of the following as confirmed by claims history or submission of medical records:

**3.1.1** ONE of the following:

- Amphetamine based stimulant (e.g., amphetamine, dextroamphetamine)
- Methylphenidate based stimulant

**AND**

**3.1.2** ONE of the following:

- Modafinil (generic Provigil)
- Armodafinil (generic Nuvigil)

**OR**

**3.2** History of contraindication or intolerance to ALL of the following drugs or classes (please specify contraindication or intolerance):

- Amphetamine based stimulant (e.g., amphetamine, dextroamphetamine)
- Methylphenidate based stimulant
- Modafinil (generic Provigil)
- Armodafinil (generic Nuvigil)

**AND**

**4** - Prescribed by ONE of the following:

- Neurologist
- Psychiatrist
- Sleep Medicine Specialist
- Pulmonologist

|                                                                                                                             |                     |
|-----------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Sunosi                                                                                                         |                     |
| Diagnosis                                                                                                                   | Narcolepsy          |
| Approval Length                                                                                                             | 12 month(s)         |
| Therapy Stage                                                                                                               | Reauthorization     |
| Guideline Type                                                                                                              | Prior Authorization |
| <b>Approval Criteria</b><br><b>1</b> - Reduction in symptoms of excessive daytime sleepiness associated with Sunosi therapy |                     |

|                     |                         |
|---------------------|-------------------------|
| Product Name:Sunosi |                         |
| Diagnosis           | Obstructive Sleep Apnea |



|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                       |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Submission of medical records (e.g., chart notes, lab values) documenting a diagnosis of obstructive sleep apnea with <b>ONE</b> of the following:</p> <p><b>1.1</b> Fifteen or more obstructive respiratory events per hour of sleep confirmed by a sleep study</p> <p style="text-align: center;"><b>OR</b></p> <p><b>1.2</b> BOTH of the following:</p> <p><b>1.2.1</b> Five or more obstructive respiratory events per hour of sleep confirmed by a sleep study</p> <p style="text-align: center;"><b>AND</b></p> <p><b>1.2.2</b> ONE or more of the following signs/symptoms are present:</p> <ul style="list-style-type: none"> <li>• Daytime sleepiness</li> <li>• Nonrestorative sleep</li> <li>• Fatigue</li> <li>• Insomnia</li> <li>• Waking up with breath holding, gasping, or choking</li> <li>• Habitual snoring noted by bed partner or other observer</li> <li>• Observed apnea</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - BOTH of the following:</p> <p><b>2.1</b> Standard treatments for the underlying airway obstruction [e.g., continuous positive airway pressure (CPAP), bi-level positive airway pressure (BiPAP)] have been used for one month or longer</p> |                       |

**AND**

**2.2** Patient is fully compliant with ongoing treatment(s) for the underlying airway obstruction

**AND**

**3** - ONE of the following:

**3.1** Failure to ONE of the following as confirmed by claims history or submission of medical records:

- Modafinil (generic Provigil)
- Armodafinil (generic Nuvigil)

**OR**

**3.2** History of contraindication or intolerance to BOTH of the following (please specify contraindication or intolerance):

- Modafinil (generic Provigil)
- Armodafinil (generic Nuvigil)

**AND**

**4** - Prescribed by ONE of the following:

- Neurologist
- Psychiatrist
- Sleep Medicine Specialist
- Pulmonologist

|                     |                         |
|---------------------|-------------------------|
| Product Name:Sunosi |                         |
| Diagnosis           | Obstructive Sleep Apnea |
| Approval Length     | 12 month(s)             |
| Therapy Stage       | Reauthorization         |

| Guideline Type                                                                                                                                                                                                                                                                                                                     | Prior Authorization |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Reduction in symptoms of excessive daytime sleepiness associated with Sunosi therapy</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Patient continues to be fully compliant with ongoing treatment(s) for the underlying airway obstruction (e.g., CPAP, BiPAP)</p> |                     |

## 2 . Revision History

| Date       | Notes                                                  |
|------------|--------------------------------------------------------|
| 11/10/2025 | Combined formularies. No changes to clinical criteria. |

Sutent



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-331198                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Guideline Name</b> | Sutent                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 8/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                                               |                                       |
|-----------------------------------------------|---------------------------------------|
| Product Name: Brand Sutent, generic sunitinib |                                       |
| Diagnosis                                     | Gastrointestinal Stromal Tumor (GIST) |
| Approval Length                               | 12 month(s)                           |
| Therapy Stage                                 | Initial Authorization                 |

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Prior Authorization       |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| <p><b>Approval Criteria</b></p> <p><b>1 - Diagnosis of gastrointestinal stromal tumor (GIST)</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>2 - ONE of the following:</b></p> <p><b>2.1</b> Disease progression on ONE of the following as confirmed by claims history or submission of medical records:</p> <ul style="list-style-type: none"> <li>• imatinib (generic Gleevec)</li> <li>• Stivarga (regorafenib)</li> <li>• Standard dose Qinlock (ripretinib)*</li> </ul> <p style="text-align: center;"><b>OR</b></p> <p><b>2.2</b> History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):</p> <ul style="list-style-type: none"> <li>• imatinib (generic Gleevec)</li> <li>• Stivarga (regorafenib)</li> </ul> <p style="text-align: center;"><b>OR</b></p> <p><b>2.3</b> SDH (succinate dehydrogenase)-deficient GIST</p> |                           |
| Notes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | *Qinlock is non-preferred |

|                                               |                            |
|-----------------------------------------------|----------------------------|
| Product Name: Brand Sutent, generic sunitinib |                            |
| Diagnosis                                     | Renal Cell Carcinoma (RCC) |
| Approval Length                               | 12 month(s)                |
| Therapy Stage                                 | Initial Authorization      |
| Guideline Type                                | Prior Authorization        |

**Approval Criteria**

1 - Diagnosis of renal cell carcinoma (RCC)

**AND**

2 - ONE of the following:

2.1 Disease has relapsed

**OR**

2.2 Disease is advanced

**OR**

2.3 BOTH of the following:

2.3.1 Used in adjuvant setting

**AND**

2.3.2 Patient has a high risk of recurrence following nephrectomy

|                                               |                                   |
|-----------------------------------------------|-----------------------------------|
| Product Name: Brand Sutent, generic sunitinib |                                   |
| Diagnosis                                     | Neuroendocrine and Adrenal Tumors |
| Approval Length                               | 12 month(s)                       |
| Therapy Stage                                 | Initial Authorization             |
| Guideline Type                                | Prior Authorization               |
| <b>Approval Criteria</b>                      |                                   |

**1 - Progressive pancreatic neuroendocrine tumors (pNET)**

|                                                                                                                                                                                                                                                                                                 |                       |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name: Brand Sutent, generic sunitinib                                                                                                                                                                                                                                                   |                       |
| Diagnosis                                                                                                                                                                                                                                                                                       | Soft Tissue Sarcoma   |
| Approval Length                                                                                                                                                                                                                                                                                 | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                   | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                  | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of ONE of the following:</p> <ul style="list-style-type: none"> <li>• Alveolar soft part sarcoma (ASPS)</li> <li>• Angiosarcoma</li> <li>• Solitary fibrous tumor/hemangiopericytoma</li> <li>• Extraskelatal myxoid chondrosarcoma</li> </ul> |                       |

|                                                                                                                                                                                                                                                       |                       |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name: Brand Sutent, generic sunitinib                                                                                                                                                                                                         |                       |
| Diagnosis                                                                                                                                                                                                                                             | Thyroid Carcinoma     |
| Approval Length                                                                                                                                                                                                                                       | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                         | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                        | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - ALL of the following:</p> <p>1.1 Diagnosis of ONE of the following:</p> <ul style="list-style-type: none"> <li>• Follicular carcinoma</li> <li>• Oncocytic carcinoma</li> <li>• Papillary carcinoma</li> </ul> |                       |

**AND**

**1.2 ONE of the following:**

- Unresectable locoregional recurrent disease
- Persistent disease
- Metastatic disease

**AND**

**1.3 ONE of the following:**

- Patient has symptomatic disease
- Patient has progressive disease

**AND**

**1.4 Disease is refractory to radioactive iodine treatment**

**OR**

**2 - ALL of the following:**

**2.1 Diagnosis of medullary thyroid carcinoma**

**AND**

**2.2 ONE of the following:**

- Patient has progressive disease
- Patient has symptomatic metastatic disease

**AND**

**2.3 ONE of the following:**



**2.3.1** Clinical trials or preferred systemic therapy options are not available or appropriate [e.g., Caprelsa (vandetanib), Cometriq (cabozantinib)]

**OR**

**2.3.2** There is progression on preferred systemic therapy options [e.g., Caprelsa (vandetanib), Cometriq (cabozantinib)]

|                                                                            |                       |
|----------------------------------------------------------------------------|-----------------------|
| Product Name:Brand Sutent, generic sunitinib                               |                       |
| Diagnosis                                                                  | Chordoma              |
| Approval Length                                                            | 12 month(s)           |
| Therapy Stage                                                              | Initial Authorization |
| Guideline Type                                                             | Prior Authorization   |
| <b>Approval Criteria</b><br><br><b>1</b> - Diagnosis of recurrent chordoma |                       |

|                                                                                                                                                                                   |                               |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|
| Product Name:Brand Sutent, generic sunitinib                                                                                                                                      |                               |
| Diagnosis                                                                                                                                                                         | Central Nervous System Cancer |
| Approval Length                                                                                                                                                                   | 12 month(s)                   |
| Therapy Stage                                                                                                                                                                     | Initial Authorization         |
| Guideline Type                                                                                                                                                                    | Prior Authorization           |
| <b>Approval Criteria</b><br><br><b>1</b> - Diagnosis of surgically inaccessible meningiomas<br><br><p style="text-align: center;"><b>AND</b></p> <b>2</b> - ONE of the following: |                               |

- Disease is recurrent
- Disease is progressive

**AND**

**3** - Further radiation is not possible

|                                                                          |                       |
|--------------------------------------------------------------------------|-----------------------|
| Product Name:Brand Sutent, generic sunitinib                             |                       |
| Diagnosis                                                                | Thymic Carcinoma      |
| Approval Length                                                          | 12 month(s)           |
| Therapy Stage                                                            | Initial Authorization |
| Guideline Type                                                           | Prior Authorization   |
| <b>Approval Criteria</b><br><br><b>1</b> - Diagnosis of thymic carcinoma |                       |

|                                                                                                                                                                                                                                                                                  |                            |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|
| Product Name:Brand Sutent, generic sunitinib                                                                                                                                                                                                                                     |                            |
| Diagnosis                                                                                                                                                                                                                                                                        | Myeloid/Lymphoid Neoplasms |
| Approval Length                                                                                                                                                                                                                                                                  | 12 month(s)                |
| Therapy Stage                                                                                                                                                                                                                                                                    | Initial Authorization      |
| Guideline Type                                                                                                                                                                                                                                                                   | Prior Authorization        |
| <b>Approval Criteria</b><br><br><b>1</b> - Diagnosis of lymphoid, myeloid, or mixed lineage neoplasms with eosinophilia<br><br><p style="text-align: center;"><b>AND</b></p> <b>2</b> - Patient has an FMS-like tyrosine kinase 3 (FLT3) rearrangement in chronic or blast phase |                            |

|                                                                                                            |                                                                                                                                                                             |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Product Name:Brand Sutent, generic sunitinib                                                               |                                                                                                                                                                             |
| Diagnosis                                                                                                  | GIST, RCC, Neuroendocrine and Adrenal Tumors, Soft Tissue Sarcoma, Thyroid Carcinoma, Chordoma, Central Nervous System Cancer, Thymic Carcinoma, Myeloid/Lymphoid Neoplasms |
| Approval Length                                                                                            | 12 month(s)                                                                                                                                                                 |
| Therapy Stage                                                                                              | Reauthorization                                                                                                                                                             |
| Guideline Type                                                                                             | Prior Authorization                                                                                                                                                         |
| <b>Approval Criteria</b><br><br>1 - Patient does not show evidence of progressive disease while on therapy |                                                                                                                                                                             |

|                                                                                                                                         |                           |
|-----------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Brand Sutent, generic sunitinib                                                                                            |                           |
| Diagnosis                                                                                                                               | NCCN Recommended Regimens |
| Approval Length                                                                                                                         | 12 month(s)               |
| Therapy Stage                                                                                                                           | Initial Authorization     |
| Guideline Type                                                                                                                          | Prior Authorization       |
| <b>Approval Criteria</b><br><br>1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium |                           |

|                                                                                            |                           |
|--------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Brand Sutent, generic sunitinib                                               |                           |
| Diagnosis                                                                                  | NCCN Recommended Regimens |
| Approval Length                                                                            | 12 month(s)               |
| Therapy Stage                                                                              | Reauthorization           |
| Guideline Type                                                                             | Prior Authorization       |
| <b>Approval Criteria</b><br><br>1 - Documentation of positive clinical response to therapy |                           |

## 2 . Revision History

| Date      | Notes                         |
|-----------|-------------------------------|
| 7/15/2025 | Updated formularies to add IN |

Symdeko



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-371244                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Guideline Name</b> | Symdeko                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 9/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                       |                       |
|-----------------------|-----------------------|
| Product Name: Symdeko |                       |
| Approval Length       | 12 month(s)           |
| Therapy Stage         | Initial Authorization |
| Guideline Type        | Prior Authorization   |

**Approval Criteria**

**1** - Diagnosis of cystic fibrosis (CF)

**AND**

**2** - Submission of laboratory result documenting ONE of the following:

**2.1** The patient is homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene

**OR**

**2.2** The patient has at least ONE mutation in the CFTR gene that is responsive to Symdeko (See Table in Background Section)

**AND**

**3** - Prescribed by, or in consultation with, a provider who specializes in the treatment of CF

|                                                                                                                                                                       |                     |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Symdeko                                                                                                                                                  |                     |
| Approval Length                                                                                                                                                       | 12 month(s)         |
| Therapy Stage                                                                                                                                                         | Reauthorization     |
| Guideline Type                                                                                                                                                        | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of positive clinical response to Symdeko therapy (e.g., improved lung function, stable lung function)</p> |                     |

## 2 . Background

**Benefit/Coverage/Program Information****Table 1: List of CFTR gene mutations responsive to Symdeko (A complete up to date list of responsive mu-tations can be referenced in the Symdeko Prescribing Information)**

|                |                    |               |        |         |         |
|----------------|--------------------|---------------|--------|---------|---------|
| 546insCTA      | E92K               | G576A         | L346P  | R117G   | S589N   |
| 711+3A→G*      | E116K              | G576A;R668C † | L967S  | R117H   | S737F   |
| 2789+5G→A*     | E193K              | G622D         | L997F  | R117L   | S912L   |
| 3272-26A→G*    | E403D              | G970D         | L1324P | R117P   | S945L * |
| 3849+10kbC→T * | E588V              | G1069R        | L1335P | R170H   | S977F*  |
| A120T          | E822K              | G1244E        | L1480P | R258G   | S1159F  |
| A234D          | E831X              | G1249R        | M152V  | R334L   | S1159P  |
| A349V          | F191V              | G1349D        | M265R  | R334Q   | S1251N  |
| A455E *        | F311del            | H939R         | M952I  | R347H * | S1255P  |
| A554E          | F311L              | H1054D        | M952T  | R347L   | T338I   |
| A1006E         | F508C              | H1375P        | P5L    | R347P   | T1036N  |
| A1067T         | F508C;<br>S1251N † | I148T         | P67L * | R352Q * | T1053I  |
| D110E          | F508del ‡          | I175V         | P205S  | R352W   | V201M   |
| D110H *        | F575Y              | I336K         | Q98R   | R553Q   | V232D   |
| D192G          | F1016S             | I601F         | Q237E  | R668C   | V562I   |

|                             |        |         |                             |          |        |
|-----------------------------|--------|---------|-----------------------------|----------|--------|
| D443Y                       | F1052V | I618T   | Q237H                       | R751L    | V754M  |
| D443Y;<br>G576A;<br>R668C † | F1074L | I807M   | Q359R                       | R792G    | V1153E |
| D579G *                     | F1099L | I980K   | Q1291R                      | R933G    | V1240G |
| D614G                       | G126D  | I1027T  | R31L                        | R1066H   | V1293G |
| D836Y                       | G178E  | I1139V  | R74Q                        | R1070Q   | W1282R |
| D924N                       | G178R  | I1269N  | R74W                        | R1070W * | Y109N  |
| D979V                       | G194R  | I1366N  | R74W;<br>D1270N †           | R1162L   | Y161S  |
| D1152H *                    | G194V  | K1060T  | R74W;<br>V201M †            | R1283M   | Y1014C |
| D1270N                      | G314E  | L15P    | R74W;<br>V201M;<br>D1270N † | R1283S   | Y1032C |
| E56K                        | G551D  | L206W * | R75Q                        | S549N    |        |
| E60K                        | G551S  | L320V   | R117C *                     | S549R    |        |

\* Clinical data for these mutations in Clinical Studies.

† Complex/compound mutations where a single allele of the CFTR gene has multiple mutations; these exist independent of the presence of mutations on the other allele.

### 3 . Revision History

| Date | Notes |
|------|-------|
|------|-------|



|           |                 |
|-----------|-----------------|
| 8/18/2025 | Removed PA CAID |
|-----------|-----------------|

Synagis



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-450216                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Guideline Name</b> | Synagis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 12/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                       |                     |
|-----------------------|---------------------|
| Product Name:Synagis* |                     |
| Diagnosis             | Prematurity         |
| Guideline Type        | Prior Authorization |

**Approval Criteria**

**1** - BOTH of the following:

**1.1** Patient is an infant born before 29 weeks, 0 days gestation

**AND**

**1.2** Patient is less than 12 months of age at the start of RSV “season”

**AND**

**2** - Administered during RSV season\*\*

**AND**

**3** - Monthly dose of Synagis does not exceed 15 milligram per kilogram per dose

**AND**

**4** - Dosage of Synagis does not exceed 5 monthly doses per single RSV “season”\*\*\*

**AND**

**5** - Patient has not previously received treatment with Beyfortus (nirsevimab-alip) or Enflonsia (clesrovimab-cfor) during or entering the current RSV “season”

**AND**

**6** - Synagis is not being requested for any of the following situations alone:

- Infants and children with hemodynamically insignificant heart disease (e.g., secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus)
- Infants with congenital heart disease and cardiac lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure
- Infants with cardiomyopathy sufficiently mild that they do not require pharmacotherapy
- Routine use of prophylaxis in children with Down syndrome [unless qualifying heart disease, CLD, airway clearance issues (the inability to clear secretions from the upper airway because of ineffective cough), or prematurity (less than 29 weeks, 0 days gestation) is present]
- Routine use of prophylaxis in children with cystic fibrosis (unless indications noted in proven indications above are present)
- Prophylaxis for primary asthma prevention or to reduce subsequent episodes of wheezing in infants and children
- Synagis prophylaxis for prevention of nosocomial disease

**AND**

**7 - The request is NOT for one of the following:**

- Administration of monthly Synagis prophylaxis after an infant or child has experienced a breakthrough RSV hospitalization during the current season if child had met criteria for palivizumab
- Treatment of symptomatic RSV disease

|       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Notes | <p>*Approval for up to 5 doses per single RSV “season.”</p> <p>**Information regarding RSV season may be found at:</p> <ul style="list-style-type: none"> <li>• Centers for Disease and Prevention (CDC) surveillance reports: <a href="https://www.cdc.gov/nrevss/php/dashboard/index.html">https://www.cdc.gov/nrevss/php/dashboard/index.html</a></li> </ul> <p>***Infants in a neonatal intensive care unit who qualify for prophylaxis may receive the first dose 48 to 72 hours before discharge to home or promptly after discharge. If the first dose is administered in the hospital, this dose will be considered the first dose of the maximum 5 dose series for the season. Any subsequent doses received in the hospital setting, are also considered as part of the maximum 5 dose series. For infants born during the RSV “season,” fewer than 5 monthly doses may be needed.</p> |
|-------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                        |                            |
|------------------------|----------------------------|
| Product Name: Synagis* |                            |
| Diagnosis              | Chronic Lung Disease (CLD) |
| Guideline Type         | Prior Authorization        |

**Approval Criteria**

**1 - ONE of the following:**

**1.1 ALL of the following for patients age 0 to less than 12 months:**

**1.1.1** The patient is a preterm infant defined as gestational age less than 32 weeks, 0 days

**AND**

**1.1.2** Patient has developed chronic lung disease (CLD) of prematurity

**AND**

**1.1.3** There was a requirement for greater than 21% oxygen for at least the first 28 days after birth

**OR**

**1.2 ALL of the following for patients age greater than or equal to 12 months to less than 24 months:**

**1.2.1** The patient was born at less than 32 weeks, 0 days gestation

**AND**

**1.2.2** The patient required at least 28 days of oxygen after birth

**AND**

**1.2.3** The patient continues to require supplemental oxygen, diuretics, or chronic systemic corticosteroid therapy within 6 months of the start of the second RSV “season”

**AND**

**2** - Administered during RSV season\*\*

**AND**

**3** - Monthly dose of Synagis does not exceed 15 milligram per kilogram per dose

**AND**

**4** - Dosage of Synagis does not exceed 5 monthly doses per single RSV “season”\*\*\*

**AND**

**5** - Patient has not previously received treatment with Beyfortus (nirsevimab-alip) or Enflonia (clesrovimab-cfor) during or entering the current RSV “season”

**AND**

**6** - Synagis is not being requested for any of the following situations alone:

- Infants and children with hemodynamically insignificant heart disease (e.g., secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus)
- Infants with congenital heart disease and cardiac lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure
- Infants with cardiomyopathy sufficiently mild that they do not require pharmacotherapy
- Routine use of prophylaxis in children with Down syndrome [unless qualifying heart disease, CLD, airway clearance issues (the inability to clear secretions from the upper airway because of ineffective cough), or prematurity (less than 29 weeks, 0 days gestation) is present]
- Routine use of prophylaxis in children with cystic fibrosis (unless indications noted in proven indications above are present)
- Prophylaxis for primary asthma prevention or to reduce subsequent episodes of wheezing in infants and children
- Synagis prophylaxis for prevention of nosocomial disease

**AND**

**7** - The request is NOT for one of the following:

|                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"> <li>Administration of monthly Synagis prophylaxis after an infant or child has experienced a breakthrough RSV hospitalization during the current season if child had met criteria for palivizumab</li> <li>Treatment of symptomatic RSV disease</li> </ul> |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Notes                                                                                                                                                                                                                                                                                         | <p>*Approval for up to 5 doses per single RSV “season.”</p> <p>**Information regarding RSV season may be found at:</p> <ul style="list-style-type: none"> <li>Centers for Disease and Prevention (CDC) surveillance reports: <a href="http://www.cdc.gov/nrevss/php/dashboard/index.html">http://www.cdc.gov/nrevss/php/dashboard/index.html</a></li> </ul> <p>***Infants in a neonatal intensive care unit who qualify for prophylaxis may receive the first dose 48 to 72 hours before discharge to home or promptly after discharge. If the first dose is administered in the hospital, this dose will be considered the first dose of the maximum 5 dose series for the season. Any subsequent doses received in the hospital setting, are also considered as part of the maximum 5 dose series. For infants born during the RSV “season,” fewer than 5 monthly doses may be needed.</p> |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|
| Product Name: Synagis*                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Congenital Heart Disease (CHD) |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Prior Authorization            |
| <p><b>Approval Criteria</b></p> <p>1 - ONE of the following:</p> <p>1.1 ONE of the following for patients age 0 to less than 12 months:</p> <p>1.1.1 Patient has hemodynamically significant congenital heart disease (CHD) including ONE of the following:</p> <ul style="list-style-type: none"> <li>Acyanotic heart disease and receiving medication to control congestive heart failure and will require cardiac surgical procedures</li> <li>Moderate to severe pulmonary hypertension</li> <li>Documentation that decisions regarding prophylaxis for infants with cyanotic heart defects were made in consultation with a pediatric cardiologist</li> </ul> <p style="text-align: center;"><b>OR</b></p> <p>1.1.2 The patient is undergoing cardiac transplantation during the RSV “season”</p> |                                |

**OR**

**1.2** BOTH of the following:

**1.2.1** The patient is greater than or equal to 12 months to less than 24 months of age

**AND**

**1.2.2** ONE of the following:

- After cardiac bypass
- At the conclusion of extracorporeal membrane oxygenation
- The patient is undergoing cardiac transplantation during the RSV “season”

**AND**

**2** - Administered during RSV season\*\*

**AND**

**3** - Monthly dose of Synagis does not exceed 15 milligram per kilogram per dose

**AND**

**4** - Dosage of Synagis does not exceed 5 monthly doses per single RSV “season”\*\*\*

**AND**

**5** - Patient has not previously received treatment with Beyfortus (nirsevimab-alip) or Enflonsia (clesrovimab-cfor) during or entering the current RSV “season”

**AND**



**6 - Synagis is not being requested for any of the following situations alone:**

- Infants and children with hemodynamically insignificant heart disease (e.g., secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus)
- Infants with congenital heart disease and cardiac lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure
- Infants with cardiomyopathy sufficiently mild that they do not require pharmacotherapy
- Routine use of prophylaxis in children with Down syndrome [unless qualifying heart disease, CLD, airway clearance issues (the inability to clear secretions from the upper airway because of ineffective cough), or prematurity (less than 29 weeks, 0 days gestation) is present]
- Routine use of prophylaxis in children with cystic fibrosis (unless indications noted in proven indications above are present)
- Prophylaxis for primary asthma prevention or to reduce subsequent episodes of wheezing in infants and children
- Synagis prophylaxis for prevention of nosocomial disease

**AND**

**7 - The request is NOT for one of the following:**

- Administration of monthly Synagis prophylaxis after an infant or child has experienced a breakthrough RSV hospitalization during the current season if child had met criteria for palivizumab
- Treatment of symptomatic RSV disease

|       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Notes | <p>*Approval for up to 5 doses per single RSV “season.”</p> <p>**Information regarding RSV season may be found at:</p> <ul style="list-style-type: none"> <li>• Centers for Disease and Prevention (CDC) surveillance reports: <a href="https://www.cdc.gov/nrevss/php/dashboard/index.html">https://www.cdc.gov/nrevss/php/dashboard/index.html</a></li> </ul> <p>***Infants in a neonatal intensive care unit who qualify for prophylaxis may receive the first dose 48 to 72 hours before discharge to home or promptly after discharge. If the first dose is administered in the hospital, this dose will be considered the first dose of the maximum 5 dose series for the season. Any subsequent doses received in the hospital setting, are also considered as part of the maximum 5 dose series. For infants born during the RSV “season,” fewer than 5 monthly doses may be needed.</p> |
|-------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                        |                                                                 |
|------------------------|-----------------------------------------------------------------|
| Product Name: Synagis* |                                                                 |
| Diagnosis              | Congenital abnormalities of the airway or neuromuscular disease |
| Guideline Type         | Prior Authorization                                             |

**Approval Criteria**

**1** - ALL of the following:

**1.1** Patient is age 0 to less than 12 months

**AND**

**1.2** Patient has ONE of the following:

- Neuromuscular disease
- A congenital anomaly that impairs the ability to clear secretions from the lower airway because of ineffective cough

**AND**

**2** - Administered during RSV season\*\*

**AND**

**3** - Monthly dose of Synagis does not exceed 15 milligram per kilogram per dose

**AND**

**4** - Dosage of Synagis does not exceed 5 monthly doses per single RSV “season”\*\*\*

**AND**

**5** - Patient has not previously received treatment with Beyfortus (nirsevimab-alip) or Enflonsia (clesrovimab-cfor) during or entering the current RSV “season”

**AND**

**6 - Synagis is not being requested for any of the following situations alone:**

- Infants and children with hemodynamically insignificant heart disease (e.g., secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus)
- Infants with congenital heart disease and cardiac lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure
- Infants with cardiomyopathy sufficiently mild that they do not require pharmacotherapy
- Routine use of prophylaxis in children with Down syndrome [unless qualifying heart disease, CLD, airway clearance issues (the inability to clear secretions from the upper airway because of ineffective cough), or prematurity (less than 29 weeks, 0 days gestation) is present]
- Routine use of prophylaxis in children with cystic fibrosis (unless indications noted in proven indications above are present)
- Prophylaxis for primary asthma prevention or to reduce subsequent episodes of wheezing in infants and children
- Synagis prophylaxis for prevention of nosocomial disease

**AND**

**7 - The request is NOT for one of the following:**

- Administration of monthly Synagis prophylaxis after an infant or child has experienced a breakthrough RSV hospitalization during the current season if child had met criteria for palivizumab
- Treatment of symptomatic RSV disease

|       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Notes | <p>*Approval for up to 5 doses per single RSV “season.”</p> <p>**Information regarding RSV season may be found at:</p> <ul style="list-style-type: none"> <li>• Centers for Disease and Prevention (CDC) surveillance reports: <a href="https://www.cdc.gov/nrevss/php/dashboard/index.html">https://www.cdc.gov/nrevss/php/dashboard/index.html</a></li> </ul> <p>***Infants in a neonatal intensive care unit who qualify for prophylaxis may receive the first dose 48 to 72 hours before discharge to home or promptly after discharge. If the first dose is administered in the hospital, this dose will be considered the first dose of the maximum 5 dose series for the season. Any subsequent doses received in the hospital setting, are also considered as part of the maximum 5 dose series. For infants born during the RSV “season,” fewer than 5 monthly doses may be needed.</p> |
|-------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                        |                                                       |
|------------------------|-------------------------------------------------------|
| Product Name: Synagis* |                                                       |
| Diagnosis              | Immunocompromised children less than 24 months of age |
| Guideline Type         | Prior Authorization                                   |

**Approval Criteria**

**1** - BOTH of the following:

**1.1** Patient is less than 24 months of age

**AND**

**1.2** The patient is immunocompromised (e.g. receiving cancer chemotherapy, undergoing hematopoietic stem cell transplantation, or solid organ transplantation)

**AND**

**2** - Administered during RSV season\*\*

**AND**

**3** - Monthly dose of Synagis does not exceed 15 milligram per kilogram per dose

**AND**

**4** - Dosage of Synagis does not exceed 5 monthly doses per single RSV “season”\*\*\*

**AND**

**5** - Patient has not previously received treatment with Beyfortus (nirsevimab-alip) or Enflonsia (clesrovimab-cfor) during or entering the current RSV “season”

**AND**

**6** - Synagis is not being requested for any of the following situations alone:

- Infants and children with hemodynamically insignificant heart disease (e.g., secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus)
- Infants with congenital heart disease and cardiac lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure
- Infants with cardiomyopathy sufficiently mild that they do not require pharmacotherapy
- Routine use of prophylaxis in children with Down syndrome [unless qualifying heart disease, CLD, airway clearance issues (the inability to clear secretions from the upper airway because of ineffective cough), or prematurity (less than 29 weeks, 0 days gestation) is present]
- Routine use of prophylaxis in children with cystic fibrosis (unless indications noted in proven indications above are present)
- Prophylaxis for primary asthma prevention or to reduce subsequent episodes of wheezing in infants and children
- Synagis prophylaxis for prevention of nosocomial disease

**AND**

**7 - The request is NOT for one of the following:**

- Administration of monthly Synagis prophylaxis after an infant or child has experienced a breakthrough RSV hospitalization during the current season if child had met criteria for palivizumab
- Treatment of symptomatic RSV disease

|       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Notes | <p>*Approval for up to 5 doses per single RSV “season.”</p> <p>**Information regarding RSV season may be found at:</p> <ul style="list-style-type: none"> <li>• Centers for Disease and Prevention (CDC) surveillance reports: <a href="https://www.cdc.gov/nrevss/php/dashboard/index.html">https://www.cdc.gov/nrevss/php/dashboard/index.html</a></li> </ul> <p>***Infants in a neonatal intensive care unit who qualify for prophylaxis may receive the first dose 48 to 72 hours before discharge to home or promptly after discharge. If the first dose is administered in the hospital, this dose will be considered the first dose of the maximum 5 dose series for the season. Any subsequent doses received in the hospital setting, are also considered as part of the maximum 5 dose series. For infants born during the RSV “season,” fewer than 5 monthly doses may be needed.</p> |
|-------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                        |                      |
|------------------------|----------------------|
| Product Name: Synagis* |                      |
| Diagnosis              | Cystic fibrosis (CF) |
| Guideline Type         | Prior Authorization  |

### **Approval Criteria**

**1** - ONE of the following:

**1.1** BOTH of the following for patients age 0 to less than 12 months:

**1.1.1** Patient has cystic fibrosis

**AND**

**1.1.2** Patient has clinical evidence of at least ONE of the following:

- Chronic lung disease (CLD)
- Nutritional compromise
- Failure to thrive defined as weight for length less than the 10th percentile on a pediatric growth chart

**OR**

**1.2** BOTH of the following:

**1.2.1** Patient is greater than or equal to 12 months to less than 24 months of age

**AND**

**1.2.2** Patient has manifestations of severe lung disease including ONE of the following:

- Previous hospitalization for pulmonary exacerbation in the first year of life
- Abnormalities on chest radiography or chest computed tomography that persists when stable
- Weight for length less than the 10th percentile on a pediatric growth chart

**AND**

**2** - Administered during RSV season\*\*

**AND**

**3** - Monthly dose of Synagis does not exceed 15 milligram per kilogram per dose

**AND**

**4** - Dosage of Synagis does not exceed 5 monthly doses per single RSV “season”\*\*\*

**AND**

**5** - Patient has not previously received treatment with Beyfortus (nirsevimab-alip) or Enflonsia (clesrovimab-cfor) during or entering the current RSV “season”

**AND**

**6** - Synagis is not being requested for any of the following situations alone:

- Infants and children with hemodynamically insignificant heart disease (e.g., secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus)
- Infants with congenital heart disease and cardiac lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure
- Infants with cardiomyopathy sufficiently mild that they do not require pharmacotherapy
- Routine use of prophylaxis in children with Down syndrome [unless qualifying heart disease, CLD, airway clearance issues (the inability to clear secretions from the upper airway because of ineffective cough), or prematurity (less than 29 weeks, 0 days gestation) is present]
- Routine use of prophylaxis in children with cystic fibrosis (unless indications noted in proven indications above are present)
- Prophylaxis for primary asthma prevention or to reduce subsequent episodes of wheezing in infants and children
- Synagis prophylaxis for prevention of nosocomial disease

**AND**

**7** - The request is NOT for one of the following:

|                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"> <li>Administration of monthly Synagis prophylaxis after an infant or child has experienced a breakthrough RSV hospitalization during the current season if child had met criteria for palivizumab</li> <li>Treatment of symptomatic RSV disease</li> </ul> |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Notes                                                                                                                                                                                                                                                                                         | <p>*Approval for up to 5 doses per single RSV “season.”</p> <p>**Information regarding RSV season may be found at:</p> <ul style="list-style-type: none"> <li>Centers for Disease and Prevention (CDC) surveillance reports: <a href="http://www.cdc.gov/nrevss/php/dashboard/index.html">http://www.cdc.gov/nrevss/php/dashboard/index.html</a></li> </ul> <p>***Infants in a neonatal intensive care unit who qualify for prophylaxis may receive the first dose 48 to 72 hours before discharge to home or promptly after discharge. If the first dose is administered in the hospital, this dose will be considered the first dose of the maximum 5 dose series for the season. Any subsequent doses received in the hospital setting, are also considered as part of the maximum 5 dose series. For infants born during the RSV “season,” fewer than 5 monthly doses may be needed.</p> |

## 2 . Background

| Benefit/Coverage/Program Information                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p><b>Additional Information</b></p> <p>Because the timing of the onset, peak, and decline of RSV activity might vary geographically, providers can adjust administration schedules based on local epidemiology. RSV seasonality in tropical climates (including southern Florida, Guam, Hawaii, Puerto Rico, U.S.-affiliated Pacific Islands, and U.S. Virgin Islands) might differ from that of most of the continental United States or be unpredictable. In Alaska, RSV seasonality is less predictable, and the duration of RSV activity is often longer than the national average duration.</p> <p>For analysis of National Respiratory and Enteric Virus Surveillance System (NREVSS) reports in the CDC Morbidity and Mortality Weekly Report, season onset is defined as the first of 2 consecutive weeks during which the mean percentage of specimens testing positive for RSV antigen is <math>\geq 10\%</math> or the mean percentage of specimens testing positive for RSV by PCR is <math>\geq 3\%</math>, whichever occurs first. RSV “season” offset is defined as the last week during which the mean percentage of positive specimens by antigen is <math>\geq 10\%</math>, or the mean percentage of positive specimens by PCR is <math>\geq 3\%</math>, whichever occurs last. Use of specimens</p> |



to determine the start of the RSV “season” requires that the number of specimens tested be statistically significant.

### 3 . Revision History

| Date       | Notes                                                                                                                 |
|------------|-----------------------------------------------------------------------------------------------------------------------|
| 11/12/2025 | Combined formularies. Updated background info. Added criteria to ensure no prior use of Enflonsia in same RSV season. |

Tabrecta



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-375409                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Guideline Name</b> | Tabrecta                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 10/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                        |                                    |
|------------------------|------------------------------------|
| Product Name: Tabrecta |                                    |
| Diagnosis              | Non-Small Cell Lung Cancer (NSCLC) |
| Approval Length        | 12 month(s)                        |
| Therapy Stage          | Initial Authorization              |

|                                                                                                                                                                                                                                                                                                                                                                               |                     |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of non-small cell lung cancer (NSCLC)</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - ONE of the following:</p> <p>2.1 Presence of mesenchymal-epithelial transition (MET) exon 14 skipping positive tumors</p> <p style="text-align: center;"><b>OR</b></p> <p>2.2 High level MET amplification in lung cancer</p> |                     |

|                                                                                                                            |                                    |
|----------------------------------------------------------------------------------------------------------------------------|------------------------------------|
| Product Name:Tabrecta                                                                                                      |                                    |
| Diagnosis                                                                                                                  | Non-Small Cell Lung Cancer (NSCLC) |
| Approval Length                                                                                                            | 12 month(s)                        |
| Therapy Stage                                                                                                              | Reauthorization                    |
| Guideline Type                                                                                                             | Prior Authorization                |
| <p><b>Approval Criteria</b></p> <p>1 - Patient does not show evidence of progressive disease while on Tabrecta therapy</p> |                                    |

|                       |                           |
|-----------------------|---------------------------|
| Product Name:Tabrecta |                           |
| Diagnosis             | NCCN Recommended Regimens |
| Approval Length       | 12 month(s)               |
| Therapy Stage         | Initial Authorization     |
| Guideline Type        | Prior Authorization       |

**Approval Criteria**

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

|                                                                                                            |                           |
|------------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Tabrecta                                                                                      |                           |
| Diagnosis                                                                                                  | NCCN Recommended Regimens |
| Approval Length                                                                                            | 12 month(s)               |
| Therapy Stage                                                                                              | Reauthorization           |
| Guideline Type                                                                                             | Prior Authorization       |
| <p><b>Approval Criteria</b></p> <p>1 - Documentation of positive clinical response to Tabrecta therapy</p> |                           |

## 2 . Revision History

| Date      | Notes                                                  |
|-----------|--------------------------------------------------------|
| 8/25/2025 | Combined formularies. No changes to clinical criteria. |

Tafinlar



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-373189                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Guideline Name</b> | Tafinlar                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Washington (ACUWA, ACUWAAHE, ACUWAC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 9/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                       |             |
|-----------------------|-------------|
| Product Name:Tafinlar |             |
| Diagnosis             | Melanoma    |
| Approval Length       | 12 month(s) |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                       |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1 - ONE of the following:</b></p> <p><b>1.1 Unresectable melanoma</b></p> <p style="text-align: center;"><b>OR</b></p> <p><b>1.2 Metastatic melanoma</b></p> <p style="text-align: center;"><b>OR</b></p> <p><b>1.3 BOTH of the following:</b></p> <p><b>1.3.1 Prescribed as adjuvant therapy for melanoma involving the lymph node(s)</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>1.3.2 Used in combination with Mekinist (trametinib)</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>2 - Cancer is positive for BRAF V600 mutation</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>3 - If the request is for Tafenlar tablets for oral solution, there is a reason or special circumstance why the patient is unable to use Tafenlar capsules (document reason or special circumstance)</b></p> |                       |

Product Name:Tafenlar

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                      |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Central Nervous System (CNS) Cancers |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 12 month(s)                          |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Initial Authorization                |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Prior Authorization                  |
| <p><b>Approval Criteria</b></p> <p><b>1 - ONE of the following:</b></p> <p><b>1.1 BOTH of the following:</b></p> <p><b>1.1.1</b> Patient has metastatic brain lesions</p> <p style="text-align: center;"><b>AND</b></p> <p><b>1.1.2</b> Tafenlar is active against primary tumor (melanoma)</p> <p style="text-align: center;"><b>OR</b></p> <p><b>1.2</b> Patient has a glioma</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2 - Cancer is positive for BRAF V600E mutation</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>3 - Used in combination with Mekinist (trametinib)</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>4 - If the request is for Tafenlar tablets for oral solution, there is a reason or special circumstance why the patient is unable to use Tafenlar capsules (document reason or special circumstance)</b></p> |                                      |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                    |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|
| Product Name:Tafinlar                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                    |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Non-Small Cell Lung Cancer (NSCLC) |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 12 month(s)                        |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Initial Authorization              |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Prior Authorization                |
| <p><b>Approval Criteria</b></p> <p><b>1 - Diagnosis of non-small cell lung cancer (NSCLC)</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>2 - Disease is ONE of the following:</b></p> <ul style="list-style-type: none"> <li>• Metastatic</li> <li>• Advanced</li> <li>• Recurrent</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>3 - Cancer is positive for BRAF V600E mutation</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>4 - ONE of the following:</b></p> <ul style="list-style-type: none"> <li>• Used in combination with Mekinist (trametinib)</li> <li>• Used as a single agent if the combination of Mekinist and Tafinlar is not tolerated</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>5 - If the request is for Tafinlar tablets for oral solution, there is a reason or special circumstance why the patient is unable to use Tafinlar capsules (document reason or special circumstance)</b></p> |                                    |



|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                       |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Tafinlar                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                       |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Thyroid Cancer        |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - ALL of the following:</p> <p>1.1 Diagnosis of anaplastic thyroid cancer (ATC)</p> <p style="text-align: center;"><b>AND</b></p> <p>1.2 Cancer is positive for BRAF V600E mutation</p> <p style="text-align: center;"><b>AND</b></p> <p>1.3 Used in combination with Mekinist (trametinib)</p> <p style="text-align: center;"><b>AND</b></p> <p>1.4 ONE of the following:</p> <p>1.4.1 Disease is ONE of the following:</p> <ul style="list-style-type: none"> <li>• Metastatic</li> <li>• Locally advanced</li> <li>• Unresectable</li> </ul> <p style="text-align: center;"><b>OR</b></p> <p>1.4.2 Prescribed as adjuvant therapy following resection</p> |                       |

**AND**

**1.5** If the request is for Tafenlar tablets for oral solution, there is a reason or special circumstance why the patient is unable to use Tafenlar capsules (document reason or special circumstance)

**OR**

**2** - ALL of the following:

**2.1** ONE of the following diagnoses:

- Follicular carcinoma
- Oncocytic carcinoma
- Papillary carcinoma

**AND**

**2.2** ONE of the following:

- Unresectable locoregional recurrent disease
- Persistent disease
- Metastatic disease

**AND**

**2.3** ONE of the following:

- Patient has symptomatic disease
- Patient has progressive disease

**AND**

**2.4** Disease is refractory to radioactive iodine treatment

**AND**

**2.5** Cancer is positive for BRAF V600 mutation

**AND**

**2.6** If the request is for Tafenlar tablets for oral solution, there is a reason or special circumstance why the patient is unable to use Tafenlar capsules (document reason or special circumstance)

|                                                                                                                                                                                                                                                                                                                                                                                                                                               |                       |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Tafenlar                                                                                                                                                                                                                                                                                                                                                                                                                         |                       |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                     | Hepatobiliary Cancers |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                               | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                 | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of ONE of the following:</p> <ul style="list-style-type: none"> <li>• Gallbladder cancer</li> <li>• Extrahepatic Cholangiocarcinoma</li> <li>• Intrahepatic Cholangiocarcinoma</li> </ul> <p><b>AND</b></p> <p><b>2</b> - Used as subsequent treatment after progression on or after systemic treatment</p> <p><b>AND</b></p> <p><b>3</b> - Disease is unresectable or metastatic</p> |                       |

**AND**

**4** - Cancer is positive for BRAF V600E mutation

**AND**

**5** - Used in combination with Mekinist (trametinib)

**AND**

**6** - If the request is for Tafinlar tablets for oral solution, there is a reason or special circumstance why the patient is unable to use Tafinlar capsules (document reason or special circumstance)

|                                                                                                                                                                                                                                                                                          |                       |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Tafinlar                                                                                                                                                                                                                                                                    |                       |
| Diagnosis                                                                                                                                                                                                                                                                                | Histiocytic Neoplasms |
| Approval Length                                                                                                                                                                                                                                                                          | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                            | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                           | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of ONE of the following:</p> <ul style="list-style-type: none"> <li>• Langerhans Cell Histiocytosis</li> <li>• Erdheim-Chester Disease</li> </ul> <p><b>AND</b></p> <p><b>2</b> - Cancer is positive for BRAF V600E mutation</p> |                       |

**AND**

**3** - If the request is for Tafenlar tablets for oral solution, there is a reason or special circumstance why the patient is unable to use Tafenlar capsules (document reason or special circumstance)

|                       |                       |
|-----------------------|-----------------------|
| Product Name:Tafenlar |                       |
| Diagnosis             | Solid Tumors          |
| Approval Length       | 12 month(s)           |
| Therapy Stage         | Initial Authorization |
| Guideline Type        | Prior Authorization   |

**Approval Criteria**

**1** - Presence of solid tumor

**AND**

**2** - Used as subsequent treatment after progression on or after systemic treatment

**AND**

**3** - Disease is unresectable or metastatic

**AND**

**4** - Cancer is positive for BRAF V600E mutation

**AND**

**5** - Used in combination with Mekinist (trametinib)

**AND**

**6** - If the request is for Tafenlar tablets for oral solution, there is a reason or special circumstance why the patient is unable to use Tafenlar capsules (document reason or special circumstance)

|                       |                                                                           |
|-----------------------|---------------------------------------------------------------------------|
| Product Name:Tafenlar |                                                                           |
| Diagnosis             | Epithelial Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer |
| Approval Length       | 12 month(s)                                                               |
| Therapy Stage         | Initial Authorization                                                     |
| Guideline Type        | Prior Authorization                                                       |

**Approval Criteria**

**1** - Diagnosis of ONE of the following:

- Epithelial Ovarian Cancer
- Fallopian Tube Cancer
- Primary Peritoneal Cancer

**AND**

**2** - ONE of the following:

- Persistent disease
- Recurrence in BRAF V600E positive tumors
- Recurrence of low-grade serous carcinoma

**AND**

**3** - Used in combination with Mekinist (trametinib)

**AND**

**4** - If the request is for Tafenlar tablets for oral solution, there is a reason or special circumstance why the patient is unable to use Tafenlar capsules (document reason or special circumstance)

|                       |                                      |
|-----------------------|--------------------------------------|
| Product Name:Tafenlar |                                      |
| Diagnosis             | Pancreatic Cancer / Ampullary Cancer |
| Approval Length       | 12 month(s)                          |
| Therapy Stage         | Initial Authorization                |
| Guideline Type        | Prior Authorization                  |

**Approval Criteria**

**1** - Diagnosis of ONE of the following:

- Pancreatic adenocarcinoma
- Ampullary adenocarcinoma

**AND**

**2** - Disease is ONE of the following:

- Metastatic
- Locally advanced
- Unresectable

**AND**

**3** - Cancer is positive for BRAF V600E mutation

**AND**

**4** - Used in combination with Mekinist (trametinib)

**AND**

**5** - If the request is for Tafenlar tablets for oral solution, there is a reason or special circumstance why the patient is unable to use Tafenlar capsules (document reason or special circumstance)

**Product Name:**Tafenlar

|                 |                       |
|-----------------|-----------------------|
| Diagnosis       | Hairy Cell Leukemia   |
| Approval Length | 12 month(s)           |
| Therapy Stage   | Initial Authorization |
| Guideline Type  | Prior Authorization   |

**Approval Criteria**

**1** - Diagnosis of hairy cell leukemia

**AND**

**2** - Used in combination with Mekinist (trametinib)

**AND**

**3** - If the request is for Tafenlar tablets for oral solution, there is a reason or special circumstance why the patient is unable to use Tafenlar capsules (document reason or special circumstance)

**Product Name:**Tafenlar

|                 |                       |
|-----------------|-----------------------|
| Diagnosis       | Salivary Gland Tumor  |
| Approval Length | 12 month(s)           |
| Therapy Stage   | Initial Authorization |



| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Prior Authorization |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of salivary gland tumor</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Disease is ONE of the following:</p> <ul style="list-style-type: none"> <li>• Recurrent and unresectable</li> <li>• Metastatic</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Cancer is positive for BRAF V600E mutation</p> <p style="text-align: center;"><b>AND</b></p> <p><b>4</b> - Used in combination with Mekinist (trametinib)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>5</b> - If the request is for Tafenlar tablets for oral solution, there is a reason or special circumstance why the patient is unable to use Tafenlar capsules (document reason or special circumstance)</p> |                     |

|                       |                                       |
|-----------------------|---------------------------------------|
| Product Name:Tafenlar |                                       |
| Diagnosis             | Gastrointestinal Stromal Tumor (GIST) |
| Approval Length       | 12 month(s)                           |
| Therapy Stage         | Initial Authorization                 |
| Guideline Type        | Prior Authorization                   |

### Approval Criteria

1 - Diagnosis of BRAF V600E-mutated gastrointestinal stromal tumor (GIST)

**AND**

2 - Disease is ONE of the following:

- Gross residual disease (R2 resection)
- Unresectable primary disease
- Tumor rupture
- Progressive
- Recurrent
- Metastatic

**AND**

3 - Used in combination with Mekinist (trametinib)

**AND**

4 - If the request is for Tafenlar tablets for oral solution, there is a reason or special circumstance why the patient is unable to use Tafenlar capsules (document reason or special circumstance)

|                       |                                                  |
|-----------------------|--------------------------------------------------|
| Product Name:Tafenlar |                                                  |
| Diagnosis             | All Indications except NCCN Recommended Regimens |
| Approval Length       | 12 month(s)                                      |
| Therapy Stage         | Reauthorization                                  |
| Guideline Type        | Prior Authorization                              |
| Approval Criteria     |                                                  |

**1 - Patient does not show evidence of progressive disease while on Tafenlar therapy**

| Product Name:Tafenlar                                                                                                                                                                                                                                                                                                                                                                                                  |                           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                              | NCCN Recommended Regimens |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                        | 12 month(s)               |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                          | Initial Authorization     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                         | Prior Authorization       |
| <p><b>Approval Criteria</b></p> <p><b>1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>2 - If the request is for Tafenlar tablets for oral solution, there is a reason or special circumstance why the patient is unable to use Tafenlar capsules (document reason or special circumstance)</b></p> |                           |

| Product Name:Tafenlar                                                                                             |                           |
|-------------------------------------------------------------------------------------------------------------------|---------------------------|
| Diagnosis                                                                                                         | NCCN Recommended Regimens |
| Approval Length                                                                                                   | 12 month(s)               |
| Therapy Stage                                                                                                     | Reauthorization           |
| Guideline Type                                                                                                    | Prior Authorization       |
| <p><b>Approval Criteria</b></p> <p><b>1 - Documentation of positive clinical response to Tafenlar therapy</b></p> |                           |

## 2 . Revision History

UnitedHealthcare Community Plan of New Jersey – Clinical Pharmacy Guidelines

| Date      | Notes               |
|-----------|---------------------|
| 8/19/2025 | Updated formularies |

Tagrisso



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-369250                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Guideline Name</b> | Tagrisso                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 9/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                        |                                     |
|------------------------|-------------------------------------|
| Product Name: Tagrisso |                                     |
| Diagnosis              | Central Nervous System (CNS) Cancer |
| Approval Length        | 12 month(s)                         |
| Therapy Stage          | Initial Authorization               |

|                                                                                                                                                                                                                                                                                 |                     |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Guideline Type                                                                                                                                                                                                                                                                  | Prior Authorization |
| <b>Approval Criteria</b><br><br><b>1</b> - Diagnosis of brain metastases from EGFR mutation-positive non-small cell lung cancer (NSCLC)<br><br><p style="text-align: center;"><b>OR</b></p> <b>2</b> - Diagnosis of leptomeningeal metastases from EGFR mutation-positive NSCLC |                     |

|                                                                                                            |                                     |
|------------------------------------------------------------------------------------------------------------|-------------------------------------|
| Product Name:Tagrisso                                                                                      |                                     |
| Diagnosis                                                                                                  | Central Nervous System (CNS) Cancer |
| Approval Length                                                                                            | 12 month(s)                         |
| Therapy Stage                                                                                              | Reauthorization                     |
| Guideline Type                                                                                             | Prior Authorization                 |
| <b>Approval Criteria</b><br><br><b>1</b> - Documentation of positive clinical response to Tagrisso therapy |                                     |

|                                                                                            |                                    |
|--------------------------------------------------------------------------------------------|------------------------------------|
| Product Name:Tagrisso                                                                      |                                    |
| Diagnosis                                                                                  | Non-Small Cell Lung Cancer (NSCLC) |
| Approval Length                                                                            | 12 month(s)                        |
| Therapy Stage                                                                              | Initial Authorization              |
| Guideline Type                                                                             | Prior Authorization                |
| <b>Approval Criteria</b><br><br><b>1</b> - Diagnosis of non-small cell lung cancer (NSCLC) |                                    |

**AND**

**2** - Disease is positive for at least ONE of the following EGFR mutations:

- Exon 19
- Exon 21 L858R
- S768I
- L861Q
- G719X
- T790M

**AND**

**3** - One of the following:

**3.1** All of the following:

- disease is stage IB, II, IIIA, or IIIB (T3, N2)
- Patient has undergone complete resection
- Patient has received previous adjuvant chemotherapy or ineligible to receive platinum-based chemotherapy

**OR**

**3.2** All of the following:

- Disease is stage II-III
- Disease is locally advanced or unresectable
- No disease progression during or following concurrent or sequential chemoradiation

**OR**

**3.3** Disease is recurrent, advanced, or metastatic

|                        |                                    |
|------------------------|------------------------------------|
| Product Name: Tagrisso |                                    |
| Diagnosis              | Non-Small Cell Lung Cancer (NSCLC) |
| Approval Length        | 12 month(s)                        |

|                                                                                                                 |                     |
|-----------------------------------------------------------------------------------------------------------------|---------------------|
| Therapy Stage                                                                                                   | Reauthorization     |
| Guideline Type                                                                                                  | Prior Authorization |
| <b>Approval Criteria</b><br>1 - Patient does not show evidence of progressive disease while on Tagrisso therapy |                     |

|                                                                                                                                     |                           |
|-------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Tagrisso                                                                                                               |                           |
| Diagnosis                                                                                                                           | NCCN Recommended Regimens |
| Approval Length                                                                                                                     | 12 month(s)               |
| Therapy Stage                                                                                                                       | Initial Authorization     |
| Guideline Type                                                                                                                      | Prior Authorization       |
| <b>Approval Criteria</b><br>1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium |                           |

|                                                                                                 |                           |
|-------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Tagrisso                                                                           |                           |
| Diagnosis                                                                                       | NCCN Recommended Regimens |
| Approval Length                                                                                 | 12 month(s)               |
| Therapy Stage                                                                                   | Reauthorization           |
| Guideline Type                                                                                  | Prior Authorization       |
| <b>Approval Criteria</b><br>1 - Documentation of positive clinical response to Tagrisso therapy |                           |

## 2 . Revision History



UnitedHealthcare Community Plan of New Jersey – Clinical Pharmacy Guidelines

| Date      | Notes                                                                |
|-----------|----------------------------------------------------------------------|
| 8/18/2025 | Updated formularies. Updated misspelled EGFR mutation type in NS CLC |

Takhzyro



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-242233                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Guideline Name</b> | Takhzyro                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 6/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                       |                       |
|-----------------------|-----------------------|
| Product Name:Takhzyro |                       |
| Therapy Stage         | Initial Authorization |
| Guideline Type        | Prior Authorization   |
|                       |                       |

## **Approval Criteria**

**1** - Diagnosis of hereditary angioedema (HAE) as confirmed by ONE of the following:

**1.1** C1 inhibitor (C1-INH) deficiency or dysfunction (Type I or II HAE) as documented by ONE of the following (per laboratory standard):

- C1-INH antigenic level below the lower limit of normal
- C1-INH functional level below the lower limit of normal

**OR**

**1.2** HAE with normal C1 inhibitor levels and ONE of the following:

**1.2.1** Confirmed presence variant(s) in the gene(s) for factor XII, angiotensin-1, plasminogen-1, kininogen-1, myoferlin, and heparan sulfate-glucosamine 3-O-sulfotransferase 6

**OR**

**1.2.2** Recurring angioedema attacks that are refractory to high-dose antihistamines with confirmed family history of angioedema

**OR**

**1.2.3** Recurring angioedema attacks that are refractory to high-dose antihistamines with unknown background de-novo mutation(s) (i.e., no family history) (HAE-unknown)

**AND**

**2** - BOTH of the following:

**2.1** For prophylaxis against HAE attacks

**AND**

**2.2** Not used in combination with other products indicated for prophylaxis against HAE attacks (e.g., Cinryze, Haegarda, Orladeyo)

**AND**

**3 - BOTH** of the following:

**3.1** Prescriber attests that patient has experienced attacks of a severity and/or frequency such that they would clinically benefit from prophylactic therapy with Takhzyro

**AND**

**3.2** Documentation of baseline HAE attack rate is greater than or equal to one attack per 4 weeks

**AND**

**4 - Prescribed by ONE** of the following:

- Immunologist
- Allergist

**AND**

**5 - ONE** of the following:

**5.1** Failure to Haegarda confirmed by claims history or submitted medical records

**OR**

**5.2** History of contraindication or intolerance to Haegarda (please specify intolerance or contraindication)

**OR**

**5.3** Patient is currently on Takhzyro therapy confirmed by claims history or submitted medical records

**AND**

**6** - ONE of the following:

**6.1** For adult and pediatric patients 12 years and older, Takhzyro 300 mg (milligrams) is given every 2 weeks\*

**OR**

**6.2** For pediatric patients 6 to less than 12 years of age, Takhzyro 150 mg is given every 2 weeks\*

**OR**

**6.3** For pediatric patients less than 6 years of age, Takhzyro 150 mg is given every 4 weeks\*\*

|       |                                                                                                                                                                           |
|-------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Notes | <p>*Adult and pediatric patients 6 years of age and older approval length: 8 months.</p> <p>**Pediatric patients less than 6 years of age approval length: 12 months.</p> |
|-------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                                                                                                                                                                                                                                                                                                                                                     |                     |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Takhzyro                                                                                                                                                                                                                                                                                                                               |                     |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                       | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                      | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of positive clinical response while on Takhzyro therapy</p> <p><b>AND</b></p> <p><b>2</b> - Reduction in the utilization of on-demand therapies used for acute attacks (e.g., Berinert, Ruconest, Firazyf, Kalbitor) as determined by claims information, while on Takhzyro therapy</p> |                     |

**AND**

**3** - Prescribed by ONE of the following:

- Immunologist
- Allergist

**AND**

**4** - BOTH of the following:

**4.1** For prophylaxis against hereditary angioedema (HAE) attacks

**AND**

**4.2** Not used in combination with other products indicated for prophylaxis against HAE attacks (e.g., Cinryze, Haegarda, Orladeyo)

**AND**

**5** - ONE of the following:

**5.1** Patient is less than 6 years of age and Takhzyro 150 mg (milligrams) is given every 4 weeks\*

**OR**

**5.2** Patient is at least 6 years of age, and BOTH of the following:

**5.2.1** Documentation of the number of acute HAE attacks in the previous 6 months, while on Takhzyro therapy

**AND**

**5.2.2** ONE of the following:

**5.2.2.1** If the patient experienced no (zero) acute HAE attacks in the previous 6 months, ONE of the following\*:

- For adult and pediatric patients 12 years of age and older, Takhzyro 300 mg is given every 4 weeks\*\*
- For pediatric patients 6 to less than 12 years of age, Takhzyro 150 mg is given every 4 weeks\*\*

**OR**

**5.2.2.2** If the patient experienced one or more HAE attacks in the previous 6 months, ONE of the following\*\*\*:

- For adult and pediatric patients 12 years of age and older, Takhzyro 300 mg is given every 2 weeks
- For pediatric patients 6 to less than 12 years of age, Takhzyro 150 mg is given every 2 weeks

|       |                                                                                                                                                                                                                                                                                                                                                                                                                   |
|-------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Notes | <p>*Patient experienced no acute HAE attacks in the previous 6 months, or is less than 6 years of age approval length: 12 months.</p> <p>**Patients experiencing unexpected breakthrough HAE attacks once switched to every 4 week dosing will require additional review to allow for 2 weeks dosing.</p> <p>***Patient experienced 1 or more HAE attacks in the previous 6 months approval length: 6 months.</p> |
|-------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

## 2 . Revision History

| Date      | Notes                 |
|-----------|-----------------------|
| 4/18/2025 | Combined formularies. |

Taltz



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-206586                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Guideline Name</b> | Taltz                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 4/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                    |                       |
|--------------------|-----------------------|
| Product Name:Taltz |                       |
| Diagnosis          | Plaque Psoriasis      |
| Approval Length    | 12 month(s)           |
| Therapy Stage      | Initial Authorization |
| Guideline Type     | Prior Authorization   |



## **Approval Criteria**

**1** - ALL of the following:

**1.1** Diagnosis of chronic moderate to severe plaque psoriasis

**AND**

**1.2** ONE of the following:

**1.2.1** ALL of the following:

**1.2.1.1** Greater than or equal to 3% body surface area involvement, palmoplantar, facial, or genital involvement, or severe scalp psoriasis

**AND**

**1.2.1.2** One of the following:

**1.2.1.2.1** Failure to ONE of the following topical therapy classes as confirmed by claims history or submission of medical records:

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin
- Coal tar

**OR**

**1.2.1.2.2** History of intolerance or contraindication to ALL of the following topical therapy classes (please specify intolerance or contraindication)

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin

- Coal tar

**AND**

**1.2.1.3** ONE of the following:

- Failure to a 3 month trial of methotrexate at the maximally indicated dose as confirmed by claims history or submission of medical records
- History of intolerance or contraindication to methotrexate (please specify intolerance or contraindication)

**OR**

**1.2.2** Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of plaque psoriasis as confirmed by claims history or submission of medical records [e.g., Cimzia (certolizumab), adalimumab, Otezla (apremilast), Skyrizi (risankizumab-rzaa), ustekinumab, Tremfya (guselkumab)]

**AND**

**1.3** One of the following:

**1.3.1** Failure to TWO of the following preferred products, as confirmed by claims history or submission of medical records:

- One of the preferred adalimumab products^
- Enbrel (etanercept)
- One of the preferred ustekinumab products^

**OR**

**1.3.2** History of intolerance or contraindication to ALL of the following preferred products (please specify intolerance or contraindication):

- One of the preferred adalimumab products^
- Enbrel (etanercept)
- One of the preferred ustekinumab products^

**AND**

**1.4 ONE of the following:**

- Failure to Cosentyx (secukinumab) as confirmed by claims history or submission of medical records
- History of contraindication or intolerance to Cosentyx (secukinumab) (please specify contraindication or intolerance)

**AND**

**1.5** Patient is NOT receiving Taltz in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

**AND**

**1.6** Prescribed by or in consultation with a dermatologist

**OR**

**2 - ALL of the following:**

**2.1** Patient is currently on Taltz therapy as confirmed by claims history or submission of medical records

**AND**

**2.2** Diagnosis of chronic moderate to severe plaque psoriasis

**AND**

**2.3** Patient is NOT receiving Taltz in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

|                                                                  |                            |
|------------------------------------------------------------------|----------------------------|
| <b>AND</b>                                                       |                            |
| <b>2.4</b> Prescribed by or in consultation with a dermatologist |                            |
| Notes                                                            | ^See Table 1 for PDL Links |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Taltz                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                           |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Psoriatic Arthritis (PsA) |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 12 month(s)               |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Initial Authorization     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Prior Authorization       |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - ALL of the following:</p> <p><b>1.1</b> Diagnosis of active psoriatic arthritis</p> <p style="text-align: center;"><b>AND</b></p> <p><b>1.2</b> ONE of the following:</p> <p><b>1.2.1</b> Failure to a 3 month trial of methotrexate at the maximally indicated dose as confirmed by claims history or submission of medical records</p> <p style="text-align: center;"><b>OR</b></p> <p><b>1.2.2</b> History of intolerance or contraindication to methotrexate (please specify intolerance or contraindication)</p> <p style="text-align: center;"><b>OR</b></p> <p><b>1.2.3</b> Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of psoriatic arthritis as confirmed by claims history or submission of medical</p> |                           |

records [e.g., Cimzia (certolizumab), adalimumab, Simponi (golimumab), ustekinumab, Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), Otezla (apremilast), Skyrizi (risankizumab)]

**AND**

**1.3** One of the following:

**1.3.1** Failure to TWO of the following preferred products as confirmed by claims history or submission of medical records

- One of the preferred adalimumab products^
- Enbrel (etanercept)
- One of the preferred ustekinumab products^

**OR**

**1.3.2** History of intolerance or contraindication to ALL of the following preferred products (please specify intolerance or contraindication)

- One of the preferred adalimumab products^
- Enbrel (etanercept)
- One of the preferred ustekinumab products^

**AND**

**1.4** ONE of the following:

- Failure to Cosentyx (secukinumab) as confirmed by claims history or submission of medical records
- History of contraindication or intolerance to Cosentyx (secukinumab) (please specify contraindication or intolerance)

**AND**

**1.5** Patient is NOT receiving Taltz in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

**AND**

**1.6** Prescribed by or in consultation with one of the following:

- Rheumatologist
- Dermatologist

**OR**

**2** - ALL of the following:

**2.1** Patient is currently on Taltz therapy as confirmed by claims history or submission of medical records

**AND**

**2.2** Diagnosis of active psoriatic arthritis

**AND**

**2.3** Patient is NOT receiving Taltz in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

**AND**

**2.4** Prescribed by or in consultation with one of the following:

- Rheumatologist
- Dermatologist

Notes

^See Table 1 for PDL Links

Product Name: Taltz

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                        |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Ankylosing Spondylitis |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 12 month(s)            |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Initial Authorization  |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Prior Authorization    |
| <p><b>Approval Criteria</b></p> <p><b>1 - ALL of the following:</b></p> <p><b>1.1</b> Diagnosis of active ankylosing spondylitis</p> <p style="text-align: center;"><b>AND</b></p> <p><b>1.2</b> ONE of the following:</p> <p><b>1.2.1</b> Failure to TWO NSAIDs (non-steroidal anti-inflammatory drugs) (e.g., ibuprofen, naproxen) at maximally indicated doses, each used for at least 4 weeks, as confirmed by claims history or submission of medical records</p> <p style="text-align: center;"><b>OR</b></p> <p><b>1.2.2</b> History of intolerance or contraindication to two NSAIDs (e.g., ibuprofen, naproxen) (please specify intolerance or contraindication)</p> <p style="text-align: center;"><b>OR</b></p> <p><b>1.2.3</b> Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of ankylosing spondylitis as confirmed by claims history or submission of medical records [e.g., adalimumab, Simponi (golimumab)].</p> <p style="text-align: center;"><b>AND</b></p> <p><b>1.3</b> One of the following:</p> <p><b>1.3.1</b> Failure to BOTH of the following as confirmed by claims history or submission of medical records:</p> |                        |

- One of the preferred adalimumab products^
- Enbrel (etanercept)

**OR**

**1.3.2** History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication)

- One of the preferred adalimumab products^
- Enbrel (etanercept)

**AND**

**1.4** ONE of the following:

- Failure to Cosentyx (secukinumab) as confirmed by claims history or submission of medical records
- History of contraindication or intolerance to Cosentyx (secukinumab) (please specify contraindication or intolerance)

**AND**

**1.5** Patient is NOT receiving Taltz in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

**AND**

**1.6** Prescribed by or in consultation with a rheumatologist

**OR**

**2** - ALL of the following:

**2.1** Patient is currently on Taltz therapy as confirmed by claims history or submission of medical records



**AND**

**2.2** Diagnosis of active ankylosing spondylitis

**AND**

**2.3** Patient is NOT receiving Taltz in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

**AND**

**2.4** Prescribed by or in consultation with a rheumatologist

|       |                            |
|-------|----------------------------|
| Notes | ^See Table 1 for PDL Links |
|-------|----------------------------|

|                                                                                                                                                                                                                                                                                                                      |                                          |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------|
| Product Name:Taltz                                                                                                                                                                                                                                                                                                   |                                          |
| Diagnosis                                                                                                                                                                                                                                                                                                            | Non-Radiographic Axial Spondyloarthritis |
| Approval Length                                                                                                                                                                                                                                                                                                      | 12 month(s)                              |
| Therapy Stage                                                                                                                                                                                                                                                                                                        | Initial Authorization                    |
| Guideline Type                                                                                                                                                                                                                                                                                                       | Prior Authorization                      |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - ALL of the following:</p> <p><b>1.1</b> Diagnosis of active non-radiographic axial spondyloarthritis</p> <p><b>AND</b></p> <p><b>1.2</b> ONE of the following:</p> <p><b>1.2.1</b> Failure to two NSAIDs (non-steroidal anti-inflammatory drugs) (e.g., ibuprofen,</p> |                                          |

naproxen) at maximally indicated doses, each used for at least 4 weeks, as confirmed by claims history or submission of medical records

**OR**

**1.2.2** History of intolerance or contraindication to two NSAIDs (e.g., ibuprofen, naproxen) (please specify intolerance or contraindication)

**OR**

**1.2.3** Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of non-radiographic axial spondyloarthritis as confirmed by claims history or submission of medical records [e.g. Cimzia (certolizumab), Cosentyx (secukinumab)]

**AND**

**1.3** ONE of the following:

- Failure to Cosentyx (secukinumab) as confirmed by claims history or submission of medical records
- History of contraindication or intolerance to Cosentyx (secukinumab) (please specify contraindication or intolerance)

**AND**

**1.4** Patient is NOT receiving Taltz in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

**AND**

**1.5** Prescribed by or in consultation with a rheumatologist

**OR**

**2** - ALL of the following:

**2.1** Patient is currently on Taltz therapy as confirmed by claims history or submission of medical records

**AND**

**2.2** Diagnosis of active non-radiographic axial spondyloarthritis

**AND**

**2.3** Patient is NOT receiving Taltz in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

**AND**

**2.4** Prescribed by or in consultation with a rheumatologist

| Product Name:Taltz                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                               |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------|
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                           | Plaque Psoriasis, Psoriatic Arthritis (PsA), Ankylosing Spondylitis, Non-Radiographic Axial Spondyloarthritis |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                     | 12 month(s)                                                                                                   |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                       | Reauthorization                                                                                               |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                      | Prior Authorization                                                                                           |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of positive clinical response to Taltz therapy</p> <p><b>AND</b></p> <p><b>2</b> - Patient is NOT receiving Taltz in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx</p> |                                                                                                               |

|                                                                                                                                                        |                                                                               |
|--------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------|
| (secukinumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]* |                                                                               |
| Notes                                                                                                                                                  | *Examples of drug(s) may not be applicable based on the requested indication. |

## 2 . Background

| Benefit/Coverage/Program Information                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p><b>Table 1: PDL Links</b></p> <p>CO: <a href="https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html</a></p> <p>HI: <a href="https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html</a></p> <p>MD: <a href="https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-cp-pharmacy.html</a></p> <p>NJ: <a href="https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html</a></p> <p>NY/NY EPP: <a href="https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html</a></p> <p>PA CHIP: <a href="https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP">https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP</a></p> <p>RI: <a href="https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html</a></p> <p>NM: <a href="https://www.uhcprovider.com/en/health-plans-by-state/new-mexico-health-plans/nm-comm-plan-home/nm-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/new-mexico-health-plans/nm-comm-plan-home/nm-cp-pharmacy.html</a></p> |

## 3 . Revision History

UnitedHealthcare Community Plan of New Jersey – Clinical Pharmacy Guidelines

| Date     | Notes                                                                         |
|----------|-------------------------------------------------------------------------------|
| 3/5/2025 | Added NM to formulary. Criteria updates. Changed "Stelara" to "ustekinumab" . |

Talzenna



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-257189                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Guideline Name</b> | Talzenna                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 7/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                       |                       |
|-----------------------|-----------------------|
| Product Name:Talzenna |                       |
| Diagnosis             | Breast Cancer         |
| Approval Length       | 12 month(s)           |
| Therapy Stage         | Initial Authorization |

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Prior Authorization |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of breast cancer</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Disease is ONE of the following:</p> <ul style="list-style-type: none"> <li>• Locally advanced</li> <li>• Metastatic</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Presence of a germline BRCA (breast cancer)-mutation</p> <p style="text-align: center;"><b>AND</b></p> <p><b>4</b> - ONE of the following:</p> <p><b>4.1</b> Patient is currently on Talzena therapy as confirmed by claims history or submitted medical records</p> <p style="text-align: center;"><b>OR</b></p> <p><b>4.2</b> History of intolerance or contraindication to Lynparza (olaparib) (please specify intolerance or contraindication)</p> <p style="text-align: center;"><b>OR</b></p> <p><b>4.3</b> Provider attests that the patient is not an appropriate candidate for Lynparza (olaparib) based on the patient's clinical status or comorbidities</p> |                     |

Product Name: Talzena

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                       |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Prostate Cancer       |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of metastatic castration-resistant prostate cancer</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Presence of homologous recombination repair (HRR) gene mutations</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Used in combination with Xtandi (enzalutamide)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>4</b> - ONE of the following:</p> <p><b>4.1</b> Used in combination with a gonadotropin-releasing hormone (GnRH) analog [e.g., Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix)]</p> <p style="text-align: center;"><b>OR</b></p> <p><b>4.2</b> Patient has had bilateral orchiectomy</p> |                       |

|                        |                                |
|------------------------|--------------------------------|
| Product Name: Talzenna |                                |
| Diagnosis              | Breast Cancer, Prostate Cancer |
| Approval Length        | 12 month(s)                    |
| Therapy Stage          | Reauthorization                |
| Guideline Type         | Prior Authorization            |



**Approval Criteria**

1 - Patient does not show evidence of progressive disease while on Talzenna therapy

Product Name:Talzenna

|           |                           |
|-----------|---------------------------|
| Diagnosis | NCCN Recommended Regimens |
|-----------|---------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Talzenna

|           |                           |
|-----------|---------------------------|
| Diagnosis | NCCN Recommended Regimens |
|-----------|---------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                 |
|---------------|-----------------|
| Therapy Stage | Reauthorization |
|---------------|-----------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

1 - Documentation of positive clinical response to Talzenna therapy

## 2 . Revision History

|      |       |
|------|-------|
| Date | Notes |
|------|-------|

|          |                                                                                        |
|----------|----------------------------------------------------------------------------------------|
| 5/5/2025 | Updated formularies. Revised wording in breast cancer section without change to intent |
|----------|----------------------------------------------------------------------------------------|

Tarceva



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-164096                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Guideline Name</b> | Tarceva                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 2/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                                                |                       |
|------------------------------------------------|-----------------------|
| Product Name: Brand Tarceva, generic erlotinib |                       |
| Diagnosis                                      | Pancreatic Cancer     |
| Approval Length                                | 12 month(s)           |
| Therapy Stage                                  | Initial Authorization |
| Guideline Type                                 | Prior Authorization   |

**Approval Criteria**

1 - Diagnosis of pancreatic cancer

**AND**

2 - Disease is ONE of the following:

- Locally advanced
- Unresectable
- Metastatic

**AND**

3 - Used in combination with gemcitabine

|                                                                                                                                                                                                                                                                          |                                    |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|
| Product Name: Brand Tarceva, generic erlotinib                                                                                                                                                                                                                           |                                    |
| Diagnosis                                                                                                                                                                                                                                                                | Non-Small Cell Lung Cancer (NSCLC) |
| Approval Length                                                                                                                                                                                                                                                          | 12 month(s)                        |
| Therapy Stage                                                                                                                                                                                                                                                            | Initial Authorization              |
| Guideline Type                                                                                                                                                                                                                                                           | Prior Authorization                |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of non-small cell lung cancer (NSCLC)</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Disease is ONE of the following:</p> <ul style="list-style-type: none"> <li>• Metastatic</li> <li>• Recurrent</li> </ul> |                                    |

- Advanced

**AND**

**3 - ONE of the following:**

- Tumors are positive for epidermal growth factor receptor (EGFR) exon 19 deletions
- Tumors are positive for exon 21 (L858R) substitution mutations
- Tumors are positive for a known sensitizing EGFR mutation (e.g., S768I, L861Q, G719X)

|                                                              |                       |
|--------------------------------------------------------------|-----------------------|
| Product Name: Brand Tarceva, generic erlotinib               |                       |
| Diagnosis                                                    | Chordoma              |
| Approval Length                                              | 12 month(s)           |
| Therapy Stage                                                | Initial Authorization |
| Guideline Type                                               | Prior Authorization   |
| <b>Approval Criteria</b><br><b>1 - Diagnosis of chordoma</b> |                       |

|                                                                   |                       |
|-------------------------------------------------------------------|-----------------------|
| Product Name: Brand Tarceva, generic erlotinib                    |                       |
| Diagnosis                                                         | Kidney Cancer         |
| Approval Length                                                   | 12 month(s)           |
| Therapy Stage                                                     | Initial Authorization |
| Guideline Type                                                    | Prior Authorization   |
| <b>Approval Criteria</b><br><b>1 - Diagnosis of kidney cancer</b> |                       |

|                                                   |  |
|---------------------------------------------------|--|
| <b>AND</b>                                        |  |
| <b>2</b> - Disease is stage IV or relapsed        |  |
| <b>AND</b>                                        |  |
| <b>3</b> - Disease is of non-clear cell histology |  |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                      |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|
| Product Name: Brand Tarceva, generic erlotinib                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                      |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Central Nervous System (CNS) Cancers |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 12 month(s)                          |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Initial Authorization                |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Prior Authorization                  |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of brain, leptomeningeal, or spine metastases from non-small cell lung cancer (NSCLC)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - ONE of the following:</p> <ul style="list-style-type: none"> <li>• Tumors are positive for epidermal growth factor receptor (EGFR) exon 19 deletions</li> <li>• Tumors are positive for exon 21 (L858R) substitution mutations</li> <li>• Tumors are positive for a known sensitizing EGFR mutation (e.g., S768I, L861Q, G719X)</li> </ul> |                                      |

|                                                |               |
|------------------------------------------------|---------------|
| Product Name: Brand Tarceva, generic erlotinib |               |
| Diagnosis                                      | Vulvar cancer |
| Approval Length                                | 12 month(s)   |

|                                                                   |                       |
|-------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                     | Initial Authorization |
| Guideline Type                                                    | Prior Authorization   |
| <b>Approval Criteria</b><br><b>1</b> - Diagnosis of vulvar cancer |                       |

|                                                                                                                       |                                                                                                                                     |
|-----------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|
| Product Name:Brand Tarceva, generic erlotinib                                                                         |                                                                                                                                     |
| Diagnosis                                                                                                             | Pancreatic Cancer, Non-Small Cell Lung Cancer (NSCLC), Chordoma, Kidney Cancer, Central Nervous System (CNS) Cancers, Vulvar Cancer |
| Approval Length                                                                                                       | 12 month(s)                                                                                                                         |
| Therapy Stage                                                                                                         | Reauthorization                                                                                                                     |
| Guideline Type                                                                                                        | Prior Authorization                                                                                                                 |
| <b>Approval Criteria</b><br><b>1</b> - Patient does not show evidence of progressive disease while on Tarceva therapy |                                                                                                                                     |

|                                                                                                                                            |                           |
|--------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Brand Tarceva, generic erlotinib                                                                                              |                           |
| Diagnosis                                                                                                                                  | NCCN Recommended Regimens |
| Approval Length                                                                                                                            | 12 month(s)               |
| Therapy Stage                                                                                                                              | Initial Authorization     |
| Guideline Type                                                                                                                             | Prior Authorization       |
| <b>Approval Criteria</b><br><b>1</b> - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium |                           |

|                                               |  |
|-----------------------------------------------|--|
| Product Name:Brand Tarceva, generic erlotinib |  |
|-----------------------------------------------|--|

|                                                                                                           |                           |
|-----------------------------------------------------------------------------------------------------------|---------------------------|
| Diagnosis                                                                                                 | NCCN Recommended Regimens |
| Approval Length                                                                                           | 12 month(s)               |
| Therapy Stage                                                                                             | Reauthorization           |
| Guideline Type                                                                                            | Prior Authorization       |
| <b>Approval Criteria</b><br><br><b>1</b> - Documentation of positive clinical response to Tarceva therapy |                           |

## 2 . Revision History

| Date      | Notes             |
|-----------|-------------------|
| 1/22/2025 | Updated GPI list. |



Targretin (bexarotene)



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-138782                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Guideline Name</b> | Targretin (bexarotene)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 2/1/2024 |
|-----------------|----------|

## 1 . Criteria

|                                                   |                           |
|---------------------------------------------------|---------------------------|
| Product Name: Brand Targretin, generic bexarotene |                           |
| Diagnosis                                         | Cutaneous T-Cell Lymphoma |
| Approval Length                                   | 12 month(s)               |
| Therapy Stage                                     | Initial Authorization     |
| Guideline Type                                    | Prior Authorization       |

**Approval Criteria**

**1** - Diagnosis of cutaneous T-cell lymphoma (CTCL)

**AND**

**2** - ONE of the following:

**2.1** Failure to at least one prior therapy (including skin-directed therapies [e.g., corticosteroids (clobetasol, diflorasone, halobetasol, augmented betamethasone dipropionate), phototherapy, or systemic therapies [e.g., interferons]] as confirmed by claims history or submission of medical records

**OR**

**2.2** History of contraindication or intolerance to at least one prior therapy (including skin-directed therapies [e.g., corticosteroids (clobetasol, diflorasone, halobetasol, augmented betamethasone dipropionate), phototherapy, or systemic therapies [e.g., interferons]] (please specify contraindication or intolerance)

|                                                                                                            |                           |
|------------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Brand Targretin, generic bexarotene                                                           |                           |
| Diagnosis                                                                                                  | Cutaneous T-Cell Lymphoma |
| Approval Length                                                                                            | 12 month(s)               |
| Therapy Stage                                                                                              | Reauthorization           |
| Guideline Type                                                                                             | Prior Authorization       |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Patient has not had disease progression while on therapy</p> |                           |

|                                                  |                           |
|--------------------------------------------------|---------------------------|
| Product Name:Brand Targretin, generic bexarotene |                           |
| Diagnosis                                        | NCCN Recommended Regimens |
| Approval Length                                  | 12 month(s)               |

|                                                                                                                                                |                       |
|------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                                                                                  | Initial Authorization |
| Guideline Type                                                                                                                                 | Prior Authorization   |
| <b>Approval Criteria</b><br><br><b>1</b> - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium |                       |

|                                                                                                   |                           |
|---------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Brand Targretin, generic bexarotene                                                  |                           |
| Diagnosis                                                                                         | NCCN Recommended Regimens |
| Approval Length                                                                                   | 12 month(s)               |
| Therapy Stage                                                                                     | Reauthorization           |
| Guideline Type                                                                                    | Prior Authorization       |
| <b>Approval Criteria</b><br><br><b>1</b> - Documentation of positive clinical response to therapy |                           |

## 2 . Revision History

| Date      | Notes                                                                                                                                                                                                                                                                            |
|-----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1/10/2024 | Updated guideline name; Removed Colorado SP (RMHCAID, RMHC HP, RMHWRP) from benefit coverage; Minor cosmetic/formatting cleanup of criteria; Removed reference to "Targretin" in reauthorization criterion for NCCN Recommended Regimens section. No changes to clinical intent. |

Tarpeyo



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-216276                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Guideline Name</b> | Tarpeyo                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 5/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                       |                     |
|-----------------------|---------------------|
| Product Name: Tarpeyo |                     |
| Approval Length       | 9 month(s)          |
| Guideline Type        | Prior Authorization |

**Approval Criteria**

**1** - Diagnosis of primary immunoglobulin A nephropathy (IgAN) confirmed by renal biopsy

**AND**

**2** - Patient is at risk for disease progression

**AND**

**3** - Used to reduce the loss of kidney function

**AND**

**4** - Estimated glomerular filtration rate (eGFR) greater than or equal to 35 mL/min/1.73 m<sup>2</sup> (milliliters/minute/1.73 square meters)

**AND**

**5** - ONE of the following:

**5.1** Patient is on a stabilized dose and receiving concomitant therapy with ONE of the following, as confirmed by claims history or submitted medical records:

- Maximally tolerated angiotensin converting enzyme (ACE) inhibitor (e.g., captopril, enalapril)
- Maximally tolerated angiotensin II receptor blocker (ARB) (e.g., candesartan, valsartan)

**OR**

**5.2** Patient has an allergy, contraindication, or intolerance to ACE inhibitors and ARBs (please specify allergy, contraindication, or intolerance)

**AND**

**6** - ONE of the following:

**6.1** Failure of ONE 30-day trial of a glucocorticoid (e.g., methylprednisolone, prednisone) confirmed by claims history or submitted medical records

**OR**

**6.2** History of intolerance or contraindication to ONE glucocorticoid (please specify intolerance or contraindication)

**AND**

**7** - Prescribed by or in consultation with a nephrologist

## 2 . Revision History

| Date      | Notes                                                  |
|-----------|--------------------------------------------------------|
| 3/18/2025 | Combined formularies. No changes to clinical criteria. |

Tasigna



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-138778                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Guideline Name</b> | Tasigna                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 2/1/2024 |
|-----------------|----------|

## 1 . Criteria

|                      |                          |
|----------------------|--------------------------|
| Product Name:Tasigna |                          |
| Diagnosis            | Chronic Myeloid Leukemia |
| Approval Length      | 12 month(s)              |
| Therapy Stage        | Initial Authorization    |
| Guideline Type       | Prior Authorization      |

**Approval Criteria**

1 - Diagnosis of chronic myeloid leukemia

**AND**

2 - ONE of the following:

2.1 Patient is not a candidate for imatinib (Gleevec) as attested by physician

**OR**

2.2 Patient is currently on Tasigna therapy

|                                                                                                                                                                                                                                                                                                                                                                                                |                                       |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|
| Product Name:Tasigna                                                                                                                                                                                                                                                                                                                                                                           |                                       |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                      | Gastrointestinal Stromal Tumor (GIST) |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                | 12 month(s)                           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                  | Initial Authorization                 |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                 | Prior Authorization                   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of progressive gastrointestinal stromal tumor (GIST)</p> <p><b>AND</b></p> <p>2 - ONE of the following:</p> <p>2.1 Failure to ALL of the following, as confirmed by claims history or submission of medical records:</p> <ul style="list-style-type: none"> <li>• Imatinib (generic Gleevec)</li> <li>• Sunitinib (generic Sutent)</li> </ul> |                                       |



- Stivarga (regorafenib)
- Qinlock (ripretinib)

**OR**

**2.2** History of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):

- Imatinib (generic Gleevec)
- Sunitinib (generic Sutent)
- Stivarga (regorafenib)
- Qinlock (ripretinib)

|                                                                                                                                         |                                         |
|-----------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|
| Product Name:Tasigna                                                                                                                    |                                         |
| Diagnosis                                                                                                                               | Acute Lymphoblastic Leukemia (Ph+B-ALL) |
| Approval Length                                                                                                                         | 12 month(s)                             |
| Therapy Stage                                                                                                                           | Initial Authorization                   |
| Guideline Type                                                                                                                          | Prior Authorization                     |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of Philadelphia chromosome-positive B-cell acute lymphoblastic leukemia (Ph+B-ALL)</p> |                                         |

|                                 |                                                                               |
|---------------------------------|-------------------------------------------------------------------------------|
| Product Name:Tasigna            |                                                                               |
| Diagnosis                       | Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes |
| Approval Length                 | 12 month(s)                                                                   |
| Therapy Stage                   | Initial Authorization                                                         |
| Guideline Type                  | Prior Authorization                                                           |
| <p><b>Approval Criteria</b></p> |                                                                               |

**1** - Diagnosis of myeloid, lymphoid or mixed lineage neoplasms with eosinophilia and ABL1 (gene) rearrangement

**AND**

**2** - Neoplasm is in blast or chronic phase

**Product Name:**Tasigna

|           |                     |
|-----------|---------------------|
| Diagnosis | Melanoma: Cutaneous |
|-----------|---------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

**1** - Diagnosis of metastatic or unresectable melanoma cutaneous tumors with activating mutations of KIT

**AND**

**2** - Used as second-line or subsequent therapy for disease progression, intolerance, and or projected risk of progression with BRAF-targeted therapy

**Product Name:**Tasigna

|           |                     |
|-----------|---------------------|
| Diagnosis | Soft Tissue Sarcoma |
|-----------|---------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

**1 - Diagnosis of pigmented villonodular synovitis/tenosynovial giant cell tumor**

| Product Name:Tasigna                                                                                                  |                                                                                                                                                                                                                                   |
|-----------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Diagnosis                                                                                                             | Chronic Myeloid Leukemia, Gastrointestinal Stromal Tumor (GIST), Acute Lymphoblastic Leukemia (Ph+B-ALL), Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes, Melanoma: Cutaneous, Soft Tissue Sarcoma |
| Approval Length                                                                                                       | 12 month(s)                                                                                                                                                                                                                       |
| Therapy Stage                                                                                                         | Reauthorization                                                                                                                                                                                                                   |
| Guideline Type                                                                                                        | Prior Authorization                                                                                                                                                                                                               |
| <b>Approval Criteria</b><br><b>1 - Patient does not show evidence of progressive disease while on Tasigna therapy</b> |                                                                                                                                                                                                                                   |

| Product Name:Tasigna                                                                                                                                                  |                           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Diagnosis                                                                                                                                                             | NCCN Recommended Regimens |
| Approval Length                                                                                                                                                       | 12 month(s)               |
| Therapy Stage                                                                                                                                                         | Initial Authorization     |
| Guideline Type                                                                                                                                                        | Prior Authorization       |
| <b>Approval Criteria</b><br><b>1 - Tasigna will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium</b> |                           |

| Product Name:Tasigna |                           |
|----------------------|---------------------------|
| Diagnosis            | NCCN Recommended Regimens |
| Approval Length      | 12 month(s)               |
| Therapy Stage        | Reauthorization           |
| Guideline Type       | Prior Authorization       |

**Approval Criteria**

1 - Documentation of positive clinical response to Tassigna therapy

**2 . Revision History**

| Date      | Notes                                                                                                                                                                                                                                 |
|-----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1/11/2024 | Updated criteria for GIST. Updated criteria for Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusions. Added Melanoma Cutaneous and Soft Tissue Sarcoma as indications for criteria per NCCN recommendations. |

Tavalisse



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-398294                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Guideline Name</b> | Tavalisse                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 10/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                        |                                       |
|------------------------|---------------------------------------|
| Product Name:Tavalisse |                                       |
| Diagnosis              | Chronic immune thrombocytopenia (ITP) |
| Approval Length        | 12 month(s)                           |
| Therapy Stage          | Initial Authorization                 |
| Guideline Type         | Prior Authorization                   |

## **Approval Criteria**

**1** - Diagnosis of chronic immune thrombocytopenia (ITP)

**AND**

**2** - ONE of the following:

**2.1** BOTH of the following:

**2.1.1** ONE of the following:

**2.1.1.1** Failure to at least ONE of the following classes confirmed by claims history or submitted medical records:

- Corticosteroids
- Immunoglobulins

**OR**

**2.1.1.2** History of contraindication or intolerance to BOTH of the following classes (please specify intolerance or contraindication):

- Corticosteroids
- Immunoglobulins

**AND**

**2.1.2** ONE of the following:

**2.1.2.1** Failure to eltrombopag (generic Promacta) confirmed by claims history or submitted medical records

**OR**

**2.1.2.2** History of contraindication or intolerance to eltrombopag (generic Promacta) (please specify intolerance or contraindication)

**OR**

**2.2** Patient is currently on Tavalisse therapy

|                                                                                                      |                                       |
|------------------------------------------------------------------------------------------------------|---------------------------------------|
| Product Name:Tavalisse                                                                               |                                       |
| Diagnosis                                                                                            | Chronic immune thrombocytopenia (ITP) |
| Approval Length                                                                                      | 12 month(s)                           |
| Therapy Stage                                                                                        | Reauthorization                       |
| Guideline Type                                                                                       | Prior Authorization                   |
| <b>Approval Criteria</b><br><br>1 - Documentation of positive clinical response to Tavalisse therapy |                                       |

## 2 . Revision History

| Date      | Notes                                                    |
|-----------|----------------------------------------------------------|
| 9/19/2025 | Updated language to say "eltrombopag (generic Promacta)" |

Tavneos



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-183190                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Guideline Name</b> | Tavneos                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Arizona (ACUAZ, ACUAZEC)</li> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania (ACUPA)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 4/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                      |                                                                       |
|----------------------|-----------------------------------------------------------------------|
| Product Name:Tavneos |                                                                       |
| Diagnosis            | ANCA (Anti-Neutrophil Cytoplasmic Autoantibody)-Associated Vasculitis |



|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                       |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of severe active ANCA (anti-neutrophil cytoplasmic autoantibody)-associated vasculitis</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Submission of medical records (e.g., chart notes, laboratory values, etc.) documenting the disease is ONE of the following types:</p> <p><b>2.1</b> Granulomatosis with polyangiitis (GPA)</p> <p style="text-align: center;"><b>OR</b></p> <p><b>2.2</b> Microscopic polyangiitis (MPA)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Patient is being treated with an initial immunosuppressive regimen to induce remission (i.e., rituximab, cyclophosphamide)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>4</b> - Tavneos is being prescribed as adjunctive treatment in combination with standard therapy (e.g., prednisone, azathioprine, mycophenolate, methotrexate, rituximab, cyclophosphamide)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>5</b> - Prescribed by ONE of the following:</p> <ul style="list-style-type: none"> <li>• Rheumatologist</li> </ul> |                       |

- Nephrologist
- Pulmonologist
- Vascular Medicine Specialist

| Product Name:Tavneos                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                       |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------|
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | ANCA (Anti-Neutrophil Cytoplasmic Autoantibody)-Associated Vasculitis |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 12 month(s)                                                           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Reauthorization                                                       |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Prior Authorization                                                   |
| <p><b>Approval Criteria</b></p> <p>1 - Patient does not show evidence of progressive disease while on Tavneos therapy</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Tavneos is being prescribed as adjunctive treatment in combination with standard therapy (e.g., prednisone, azathioprine, mycophenolate, methotrexate, rituximab, cyclophosphamide)</p> <p style="text-align: center;"><b>AND</b></p> <p>3 - Prescribed by or in consultation with ONE of the following:</p> <ul style="list-style-type: none"> <li>• Rheumatologist</li> <li>• Nephrologist</li> <li>• Pulmonologist</li> <li>• Vascular Medicine Specialist</li> </ul> |                                                                       |

## 2 . Revision History

| Date      | Notes                                                  |
|-----------|--------------------------------------------------------|
| 2/20/2025 | Combined formularies. No changes to clinical criteria. |



Tazverik



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-242232                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Guideline Name</b> | Tazverik                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Washington (ACUWA, ACUWAAHE, ACUWAC)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 6/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                       |                     |
|-----------------------|---------------------|
| Product Name:Tazverik |                     |
| Diagnosis             | Epithelioid Sarcoma |
| Approval Length       | 12 month(s)         |

|                                                                                                                                                                                                                                                                                                                                                                          |                       |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                            | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                           | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of epithelioid sarcoma</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Disease is ONE of the following:</p> <ul style="list-style-type: none"> <li>• Metastatic</li> <li>• Locally advanced</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p>3 - Disease is not eligible for complete resection</p> |                       |

|                                                                                                                                                                                                                                                                                  |                       |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Tazverik                                                                                                                                                                                                                                                            |                       |
| Diagnosis                                                                                                                                                                                                                                                                        | Follicular Lymphoma   |
| Approval Length                                                                                                                                                                                                                                                                  | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                    | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                   | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of relapsed or refractory follicular lymphoma</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - ONE of the following:</p> <p>2.1 Subsequent therapy in EZH2 (gene) mutation positive disease after 2 prior therapies</p> |                       |

**OR**

**2.2** Second-line therapy irrespective of EZH2 mutation status for older or infirm patients with indications for treatment (i.e., other therapy options are not expected to be tolerable)

**OR**

**2.3** Third-line and/or subsequent therapy (if not previously given) irrespective of EZH2 mutation status in patients with indications for treatment

|                                                                                                                        |                                          |
|------------------------------------------------------------------------------------------------------------------------|------------------------------------------|
| Product Name:Tazverik                                                                                                  |                                          |
| Diagnosis                                                                                                              | Epithelioid Sarcoma, Follicular Lymphoma |
| Approval Length                                                                                                        | 12 month(s)                              |
| Therapy Stage                                                                                                          | Reauthorization                          |
| Guideline Type                                                                                                         | Prior Authorization                      |
| <b>Approval Criteria</b><br><b>1</b> - Patient does not show evidence of progressive disease while on Tazverik therapy |                                          |

|                                                                                                                                            |                           |
|--------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Tazverik                                                                                                                      |                           |
| Diagnosis                                                                                                                                  | NCCN Recommended Regimens |
| Approval Length                                                                                                                            | 12 month(s)               |
| Therapy Stage                                                                                                                              | Initial Authorization     |
| Guideline Type                                                                                                                             | Prior Authorization       |
| <b>Approval Criteria</b><br><b>1</b> - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium |                           |

|                                                                                                     |                           |
|-----------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Tazverik                                                                               |                           |
| Diagnosis                                                                                           | NCCN Recommended Regimens |
| Approval Length                                                                                     | 12 month(s)               |
| Therapy Stage                                                                                       | Reauthorization           |
| Guideline Type                                                                                      | Prior Authorization       |
| <b>Approval Criteria</b><br><br>1 - Documentation of positive clinical response to Tazverik therapy |                           |

## 2 . Revision History

| Date      | Notes                                                                                                |
|-----------|------------------------------------------------------------------------------------------------------|
| 4/18/2025 | Combined formularies. Updated GPI entry in product details section. No changes to clinical criteria. |

Tegsedi



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-138803                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Guideline Name</b> | Tegsedi                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 2/1/2024 |
|-----------------|----------|

## 1 . Criteria

|                      |                                                                           |
|----------------------|---------------------------------------------------------------------------|
| Product Name:Tegsedi |                                                                           |
| Diagnosis            | Hereditary transthyretin-mediated (hATTR) amyloidosis with polyneuropathy |
| Approval Length      | 12 month(s)                                                               |
| Therapy Stage        | Initial Authorization                                                     |
| Guideline Type       | Prior Authorization                                                       |



### **Approval Criteria**

**1** - BOTH of the following:

- Diagnosis of Hereditary transthyretin-mediated (hATTR) amyloidosis with polyneuropathy
- Documentation that the patient has a pathogenic transthyretin (TTR) mutation (e.g., V30M)

**AND**

**2** - Prescribed by or in consultation with a neurologist

**AND**

**3** - Documentation of ONE of the following:

- Patient has a baseline polyneuropathy disability (PND) score less than or equal to IIIb
- Patient has a baseline familial amyloidotic polyneuropathy (FAP) Stage 1 or 2
- Patient has a baseline neuropathy impairment (NIS) score greater than or equal to 10 and less than or equal to 130

**AND**

**4** - Patient has not had a liver transplant

**AND**

**5** - Presence of clinical signs and symptoms of the disease (e.g., peripheral sensorimotor polyneuropathy, autonomic neuropathy, motor disability, etc.)

**AND**

**6** - Patient is not receiving Tegsedi in combination with ONE of the following:

- Oligonucleotide agents [e.g., Onpattro (patisiran), Amvuttra (vutrisiran)]
- Tafamidis (e.g., Vyndaqel, Vyndamax)

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------|
| Product Name:Tegsedi                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                           |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Hereditary transthyretin-mediated (hATTR) amyloidosis with polyneuropathy |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 12 month(s)                                                               |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Reauthorization                                                           |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Prior Authorization                                                       |
| <p><b>Approval Criteria</b></p> <p>1 - Documentation that the patient has experienced a positive clinical response to Tegsedi therapy (e.g., improved neurologic impairment, motor function, quality of life, slowing of disease progression, etc.)</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Patient is not receiving Tegsedi in combination with ONE of the following:</p> <ul style="list-style-type: none"> <li>• Oligonucleotide agents [e.g., Onpattro (patisiran), Amvuttra (vutrisiran)]</li> <li>• Tafamidis (e.g., Vyndaqel, Vyndamax)</li> </ul> |                                                                           |

## 2 . Revision History

| Date      | Notes                                        |
|-----------|----------------------------------------------|
| 1/10/2024 | Update to simplify reauthorization criteria. |

Tepmetko



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-268191                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Guideline Name</b> | Tepmetko                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Washington (ACUWA, ACUWAAHE, ACUWAC)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 7/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                       |                            |
|-----------------------|----------------------------|
| Product Name:Tepmetko |                            |
| Diagnosis             | Non-Small Cell Lung Cancer |
| Approval Length       | 12 month(s)                |

|                                                                                                                                                                                                                                                                                                    |                       |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                                                                                                                                                                                                                                      | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                     | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of non-small cell lung cancer</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Disease is recurrent, advanced, or metastatic</p> <p style="text-align: center;"><b>AND</b></p> <p>3 - Tumor is MET exon 14 skipping mutation positive</p> |                       |

|                                                                                                                            |                            |
|----------------------------------------------------------------------------------------------------------------------------|----------------------------|
| Product Name:Tepmetko                                                                                                      |                            |
| Diagnosis                                                                                                                  | Non-Small Cell Lung Cancer |
| Approval Length                                                                                                            | 12 month(s)                |
| Therapy Stage                                                                                                              | Reauthorization            |
| Guideline Type                                                                                                             | Prior Authorization        |
| <p><b>Approval Criteria</b></p> <p>1 - Patient does not show evidence of progressive disease while on Tepmetko therapy</p> |                            |

|                       |                           |
|-----------------------|---------------------------|
| Product Name:Tepmetko |                           |
| Diagnosis             | NCCN Recommended Regimens |
| Approval Length       | 12 month(s)               |
| Therapy Stage         | Initial Authorization     |
| Guideline Type        | Prior Authorization       |

**Approval Criteria**

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

|                                                                                                            |                           |
|------------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Tepmetko                                                                                      |                           |
| Diagnosis                                                                                                  | NCCN Recommended Regimens |
| Approval Length                                                                                            | 12 month(s)               |
| Therapy Stage                                                                                              | Reauthorization           |
| Guideline Type                                                                                             | Prior Authorization       |
| <p><b>Approval Criteria</b></p> <p>1 - Documentation of positive clinical response to Tepmetko therapy</p> |                           |

## 2 . Revision History

| Date      | Notes                                                  |
|-----------|--------------------------------------------------------|
| 5/16/2025 | Combined formularies. No changes to clinical criteria. |

## Test Strips



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-369222                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Guideline Name</b> | Test Strips                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Michigan (ACUMI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Washington (ACUWA, ACUWAAHE, ACUWAC)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 9/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                                        |             |
|----------------------------------------|-------------|
| Product Name:Non-preferred Test Strips |             |
| Approval Length                        | 12 month(s) |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                              |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Prior Authorization          |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - If the request is non-preferred*, ONE of the following:</p> <p><b>1.1</b> Failure of both of the following preferred test strip products confirmed by claims history or submitted medical records:</p> <ul style="list-style-type: none"> <li>• Accu-Chek Test Strips</li> <li>• Contour Test Strips</li> </ul> <p style="text-align: center;"><b>OR</b></p> <p><b>1.2</b> History of intolerance or contraindication to both of the following preferred test strip products (please specify intolerance or contraindication):</p> <ul style="list-style-type: none"> <li>• Accu-Chek Test Strips</li> <li>• Contour Test Strips</li> </ul> <p style="text-align: center;"><b>OR</b></p> <p><b>1.3</b> Patient is on an insulin pump</p> |                              |
| Notes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | *See PDL links in Background |

|                                                                                                                                                                                                                                                                        |                |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|
| Product Name:All Test Strips                                                                                                                                                                                                                                           |                |
| Approval Length                                                                                                                                                                                                                                                        | 12 month(s)    |
| Guideline Type                                                                                                                                                                                                                                                         | Quantity Limit |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - If the patient is insulin dependent or pregnant, the physician must confirm the patient requires a greater quantity because of more frequent blood glucose testing (e.g., patients on intravenous insulin infusions)</p> |                |

**OR**

**2** - If the patient is not insulin dependent nor pregnant, **ONE** the following:

- The patient is experiencing or is prone to hypoglycemia or hyperglycemia and requires additional testing to achieve glycemic control
- The patient's physician is adjusting medications and the patient requires additional blood glucose testing during this time
- The patient's physician is adjusting MNT (medical nutrition therapy) and the patient requires additional blood glucose testing during this time
- The patient requires additional testing due to fluctuations in blood glucose due to physical activity/exercise
- Other circumstances where prescribing physician confirms that the patient requires a greater quantity because of more frequent blood glucose testing (clinical review required by UnitedHealthcare reviewing pharmacist and/or medical director)

Notes

The quantity limit for insulin-dependent and pregnant patients is 6 test strips/day. The quantity limit for non-insulin dependent and non-pregnant patients is 2 test strips/day.

## 2 . Background

### Benefit/Coverage/Program Information

**PDL links** CO: <https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html>

HI: <https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html>

MD: <https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-cp-pharmacy.html>

NJ: <https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html>

NY/NY EPP: <https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html>



|                                                                                                                                                                                                                                                                                        |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| PA CHIP: <a href="https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP">https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP</a> |
| RI: <a href="https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html</a>                            |
| MI: <a href="https://www.uhcprovider.com/en/health-plans-by-state/michigan-health-plans/mi-comm-plan-home/mi-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/michigan-health-plans/mi-comm-plan-home/mi-cp-pharmacy.html</a>                                    |
| VA: <a href="https://www.uhcprovider.com/en/health-plans-by-state/virginia-health-plans/va-comm-plan-home/va-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/virginia-health-plans/va-comm-plan-home/va-cp-pharmacy.html</a>                                    |
| WA: <a href="https://www.uhcprovider.com/en/health-plans-by-state/washington-health-plans/wa-comm-plan-home/wa-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/washington-health-plans/wa-comm-plan-home/wa-cp-pharmacy.html</a>                                |
| NE: <a href="https://www.uhcprovider.com/en/health-plans-by-state/nebraska-health-plans/ne-comm-plan-home/ne-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/nebraska-health-plans/ne-comm-plan-home/ne-cp-pharmacy.html</a>                                    |
| NM: <a href="https://www.uhcprovider.com/en/health-plans-by-state/new-mexico-health-plans/nm-comm-plan-home/nm-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/new-mexico-health-plans/nm-comm-plan-home/nm-cp-pharmacy.html</a>                                |

### 3 . Revision History

| Date      | Notes                                                                                                                                                              |
|-----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 8/14/2025 | Updated formularies to remove ACUAZ/ACUAZEC as they will follow FFS/state criteria instead for eff 9/1/2025. Updated background section to remove PDL link for AZ. |

## Testosterone



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-231193                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Guideline Name</b> | Testosterone                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 5/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                                                                                                                                                                                                                                                                                                                                                                                  |                        |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|
| Product Name: Androderm, generic testosterone gel, Brand Androgel, generic testosterone gel pump, Brand Androgel Pump, testosterone soln, Brand Fortesta, generic testosterone TD gel, Natesto, Brand Testim, Brand Vogelxo, Brand Vogelxo Pump, Xyosted, Jatenzo, Kyzatrex, Tlando, Brand Depo-Testosterone, generic testosterone cypionate, testosterone enanthate, Undecatrex |                        |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                        | Hypogonadism           |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                  | 12 month(s)            |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                    | Initial Authorization* |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                   | Prior Authorization    |

## **Approval Criteria**

**1** - ONE of the following:

**1.1** TWO pre-treatment serum total testosterone levels less than 300 ng/dL (nanograms/deciliter) [less than 10.4 nmol/L (nanomoles/liter)] or less than the reference range for the lab, taken at separate times (This may require treatment to be temporarily held. Document lab value and date for both levels)

**OR**

**1.2** BOTH of the following:

**1.2.1** Patient has a condition that may cause altered sex-hormone binding globulin (SHBG) [e.g., thyroid disorder, HIV (human immunodeficiency virus) disease, liver disorder, diabetes, obesity]

**AND**

**1.2.2** ONE pre-treatment calculated free or bioavailable testosterone level less than 50 pg/mL (picograms/milliliter) (< 5 ng/dL or < 0.17 nmol/L) or less than the reference range for the lab (This may require treatment to be temporarily held. Document lab value and date)

**OR**

**1.3** Patient has a history of ONE of the following:

- Bilateral orchiectomy
- Panhypopituitarism
- A genetic disorder known to cause hypogonadism (e.g., congenital anorchia, Klinefelter's syndrome)

**AND**

**2** - Patient is NOT taking any of the following growth hormones, unless diagnosed with panhypopituitarism:

- Genotropin

- Humatrope
- Norditropin FlexPro
- Nutropin AQ
- Omnitrope
- Saizen

**AND**

**3** - Patient is NOT taking any aromatase inhibitor [e.g., Arimidex (anastrozole), Femara (letrozole), Aromasin (exemestane)]

**AND**

**4** - Patient was male at birth

**AND**

**5** - Diagnosis of hypogonadism

**AND**

**6** - ONE of the following:

- Significant reduction in weight (less than 90% ideal body weight) [e.g., AIDS (acquired immunodeficiency syndrome) wasting syndrome]
- Osteopenia
- Osteoporosis
- Decreased bone density
- Decreased libido
- Organic cause of testosterone deficiency (e.g., injury, tumor, infection, or genetic defects)

**AND**

**7** - ONE of the following:

**7.1** If the request is for a non-preferred\*\* topical testosterone (gel, solution) or testosterone transdermal systems (patches), ONE of the following:

**7.1.1** Failure to ONE of the following, confirmed by claims history or submitted medical records

- generic testosterone 1% topical gel
- testosterone 1.62% pump (generic Androgel 1.62% pump)

**OR**

**7.1.2** History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- generic testosterone 1% topical gel
- testosterone 1.62% pump (generic Androgel 1.62% pump)

**OR**

**7.2** If the request is for Xyosted, BOTH of the following:

**7.2.1** ONE of the following:

**7.2.1.1** Failure to testosterone cypionate injection (generic Depo-Testosterone), confirmed by claims history or submitted medical records

**OR**

**7.2.1.2** History of intolerance or contraindication to testosterone cypionate injection (generic Depo-Testosterone) (please specify intolerance or contraindication)

**AND**

**7.2.2** ONE of the following:

**7.2.2.1** Failure to intramuscular testosterone enanthate injection, confirmed by claims history or submitted medical records

**OR**

**7.2.2.2** History of intolerance or contraindication to intramuscular testosterone enanthate injection (please specify intolerance or contraindication)

**OR**

**7.3** If the request is for Jatenzo, Kyzatrex, Tlando, or Undecatrex, ONE of the following:

**7.3.1** Failure to ALL of the following:

- testosterone cypionate vials
- testosterone enanthate vials
- testosterone gel - tube, pack, or pump bottle, or testosterone 1.62% pump (generic Androgel 1.62% pump)

**OR**

**7.3.2** History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication):

- testosterone cypionate vials
- testosterone enanthate vials
- testosterone gel - tube, pack, or pump bottle or testosterone 1.62% pump (generic Androgel 1.62% pump)

|       |                                                                                                                                                                        |
|-------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Notes | <p>*Patients that have previously received injectable testosterone open a ccess should be reviewed using reauthorization criteria</p> <p>**PDL links in Background</p> |
|-------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

Product Name: Androderm, generic testosterone gel, Brand Androgel, generic testosterone gel pump, Brand Androgel Pump, testosterone soln, Brand Fortesta, generic testosterone TD gel, Natesto, Brand Testim, Brand Vogelxo, Brand Vogelxo Pump, Xyosted, Jatenzo, Kyzatrex, Tlando, Brand Depo-Testosterone, generic testosterone cypionate, testosterone enanthate, Undecatrex

|                 |                        |
|-----------------|------------------------|
| Diagnosis       | Gender Dysphoria       |
| Approval Length | 12 month(s)            |
| Therapy Stage   | Initial Authorization* |
| Guideline Type  | Prior Authorization    |

### **Approval Criteria**

**1** - Patient is using hormones to change physical characteristics to align with gender expression

**AND**

**2** - Patient must be diagnosed with gender dysphoria, as defined by the current version of the Diagnostic and Statistical Manual of Mental Disorders (DSM)

**AND**

**3** - Patient is NOT taking any of the following growth hormones, unless diagnosed with panhypopituitarism:

- Genotropin
- Humatrope
- Norditropin FlexPro
- Nutropin AQ
- Omnitrope
- Saizen

**AND**

**4** - Patient is NOT taking any aromatase inhibitors [e.g., Arimidex (anastrozole), Femara (letrozole), Aromasin (exemestane)]

**AND**

**5** - ONE of the following:

**5.1** If the request is for a non-preferred\*\* topical testosterone (gel, solution) or testosterone transdermal systems (patches), ONE of the following:

**5.1.1** Failure to ONE of the following, confirmed by claims history or submitted medical records:

- generic testosterone 1% topical gel

- testosterone 1.62% pump (generic Androgel 1.62% pump)

**OR**

**5.1.2** History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- generic testosterone 1% topical gel
- testosterone 1.62% pump (generic Androgel 1.62% pump)

**OR**

**5.2** If the request is for Xyosted, BOTH of the following:

**5.2.1** ONE of the following:

**5.2.1.1** Failure to testosterone cypionate injection (generic Depo-Testosterone), confirmed by claims history or submitted medical records

**OR**

**5.2.1.2** History of intolerance or contraindication to testosterone cypionate injection (generic Depo-Testosterone) (please specify intolerance or contraindication)

**AND**

**5.2.2** ONE of the following:

**5.2.2.1** Failure to intramuscular testosterone enanthate injection, confirmed by claims history or submitted medical records

**OR**

**5.2.2.2** History of intolerance or contraindication to intramuscular testosterone enanthate injection (please specify intolerance or contraindication)

**OR**



**5.3** If the request is for Jatenzo, Kyzatrex, Tlando, or Undecatrex, ONE of the following:

**5.3.1** Failure to ALL of the following:

- testosterone cypionate vials
- testosterone enanthate vials
- testosterone gel - tube, pack, or pump bottle or testosterone 1.62% pump (generic Androgel 1.62% pump)

**OR**

**5.3.2** History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication):

- testosterone cypionate vials
- testosterone enanthate vials
- testosterone gel - tube, pack, or pump bottle or testosterone 1.62% pump (generic Androgel 1.62% pump)

|       |                                                                                                                                                            |
|-------|------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Notes | *Patients that have previously received injectable testosterone open access should be reviewed using reauthorization criteria<br>**PDL links in Background |
|-------|------------------------------------------------------------------------------------------------------------------------------------------------------------|

Product Name: Androderm, generic testosterone gel, Brand Androgel, generic testosterone gel pump, Brand Androgel Pump, testosterone soln, Brand Fortesta, generic testosterone TD gel, Natesto, Brand Testim, Brand Vogelxo, Brand Vogelxo Pump, Xyosted, Jatenzo, Kyzatrex, Tlando, Brand Depo-Testosterone, generic testosterone cypionate, testosterone enanthate, Undecatrex

|                 |                                |
|-----------------|--------------------------------|
| Diagnosis       | Hypogonadism, Gender Dysphoria |
| Approval Length | 12 month(s)                    |
| Therapy Stage   | Reauthorization                |
| Guideline Type  | Prior Authorization            |

### Approval Criteria

**1** - ONE of the following:

**1.1** Patient has a history of ONE of the following:

- Bilateral orchiectomy
- Panhypopituitarism
- A genetic disorder known to cause hypogonadism (e.g., congenital anorchia, Klinefelter's syndrome)

**OR**

**1.2 BOTH of the following:**

**1.2.1** Patient has a diagnosis of ONE of the following:

- Hypogonadism
- Gender dysphoria, as defined by the current version of the Diagnostic and Statistical Manual of Mental Disorders (DSM)

**AND**

**1.2.2 ONE of the following:**

**1.2.2.1** Follow-up total serum testosterone level drawn within the past 12 months is within or below the normal male limits of the reporting lab (document value and date)

**OR**

**1.2.2.2** Follow-up total serum testosterone level drawn within the past 12 months is outside of upper male limits of normal for the reporting lab and the dose is adjusted (document value and date)

**OR**

**1.2.2.3 BOTH of the following:**

**1.2.2.3.1** Patient has a condition that may cause altered sex-hormone binding globulin (SHBG) [e.g., thyroid disorder, HIV (human immunodeficiency virus) disease, liver disorder, diabetes, obesity]

**AND**

**1.2.2.3.2 ONE of the following:**

- Follow-up calculated free or bioavailable testosterone level drawn within the past 12 months is within or below the normal male limits of the reporting lab (document lab value and date)
- Follow-up calculated free or bioavailable testosterone level drawn within the past 12 months is outside of upper male limits of normal for the reporting lab and the dose is adjusted (document value and date)

**AND**

**2 - Patient is NOT taking any of the following growth hormones, unless diagnosed with panhypopituitarism:**

- Genotropin
- Humatrope
- Norditropin FlexPro
- Nutropin AQ
- Omnitrope
- Saizen

**AND**

**3 - Patient is NOT taking any aromatase inhibitors [e.g., Arimidex (anastrozole), Femara (letrozole), Aromasin (exemestane)]**

## 2 . Background

| Benefit/Coverage/Program Information                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p><b>PDL links</b></p> <p>CO: <a href="https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html</a></p> <p>HI: <a href="https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html</a></p> <p>NJ: <a href="https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html</a></p> |

NM: <https://www.uhcprovider.com/en/health-plans-by-state/new-mexico-health-plans/nm-comm-plan-home/nm-cp-pharmacy.html>

NY/NY EPP: <https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html>

PA CHIP: <https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP>

### 3 . Revision History

| Date      | Notes                                                                                     |
|-----------|-------------------------------------------------------------------------------------------|
| 3/26/2025 | Combined formularies. Updated gender dysphoria language. Updated PDL links in background. |

Tezspire



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-401248                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Guideline Name</b> | Tezspire                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 10/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                                          |                                                                 |
|------------------------------------------|-----------------------------------------------------------------|
| Product Name: Tezspire auto-injector pen |                                                                 |
| Diagnosis                                | Severe Asthma                                                   |
| Approval Length                          | 6 month(s)                                                      |
| Therapy Stage                            | Initial Authorization - Transitioning from UHC medical benefits |
| Guideline Type                           | Prior Authorization                                             |

**Approval Criteria**

**1** - Patient has been established on therapy with Tezspire under an active UnitedHealthcare medical benefit prior authorization for the treatment of severe asthma

**AND**

**2** - Documentation of positive clinical response to Tezspire therapy as demonstrated by at least ONE of the following:

**2.1** Reduction in the frequency of exacerbations

**OR**

**2.2** Decreased utilization of rescue medications

**OR**

**2.3** Increase in percent predicted FEV1 (forced expiratory volume in 1 second) from pretreatment baseline

**OR**

**2.4** Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.)

**AND**

**3** - Tezspire is being used in combination with an inhaled corticosteroid (ICS)-containing maintenance medication [e.g., Advair/AirDuo Respiclick (fluticasone propionate/salmeterol), Symbicort (budesonide/formoterol), Breo Ellipta (fluticasone furoate/vilanterol)]

**AND**

**4** - Patient is NOT receiving Tezspire in combination with any of the following for treatment of the same indication:

- Anti-interleukin-5 therapy [e.g., Cinqair (reslizumab), Fasenra (benralizumab), Nucala (mepolizumab)]
- Anti-IgE-therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin-4 therapy [e.g., Dupixent (dupilumab)]

**AND**

**5** - Prescribed by ONE of the following:

- Allergist
- Immunologist
- Pulmonologist

|                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                     |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------|
| Product Name: Tezspire auto-injector pen                                                                                                                                                                                                                                                                                                                                                                                              |                                                                     |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                             | Severe Asthma                                                       |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                       | 6 month(s)                                                          |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                         | Initial Authorization - Not transitioning from UHC medical benefits |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                        | Prior Authorization                                                 |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of severe asthma</p> <p><b>AND</b></p> <p><b>2</b> - Classification of asthma as uncontrolled or inadequately controlled as defined by at least ONE of the following:</p> <p><b>2.1</b> Poor symptom control (e.g., Asthma Control Questionnaire [ACQ] score consistently greater than 1.5 or Asthma Control test [ACT] score consistently less than 20)</p> <p><b>OR</b></p> |                                                                     |

**2.2** Two or more bursts of systemic corticosteroids for at least 3 days each in the previous 12 months

**OR**

**2.3** Asthma-related emergency treatment (e.g., emergency room visit, hospital admission, or unscheduled physician's office visit for nebulizer or other urgent treatment)

**OR**

**2.4** Airflow limitation (e.g., after appropriate bronchodilator withhold forced expiratory volume in 1 second [FEV1] less than 80% predicted [in the face of reduced FEV1/forced vital capacity [FVC] defined as less than the lower limit of normal])

**OR**

**2.5** Patient is currently dependent on oral corticosteroids for the treatment of asthma

**AND**

**3** - Tezspire will be used in combination with ONE of the following:

**3.1** ONE maximally-dosed (appropriately adjusted for age) combination inhaled corticosteroid (ICS)/long-acting beta2 agonist (LABA) product [e.g., Advair/AirDuo Resplick (fluticasone propionate/salmeterol), Symbicort (budesonide/formoterol), Breo Ellipta (fluticasone furoate/vilanterol)]

**OR**

**3.2** Combination therapy including BOTH of the following:

**3.2.1** ONE maximally-dosed (appropriately adjusted for age) ICS product [e.g., ciclesonide (Alvesco), mometasone furoate (Asmanex), beclomethasone dipropionate (QVAR)]

**AND**



**3.2.2** ONE additional asthma controller medication [e.g., LABA - olodaterol (Striverdi) or indacaterol (Arcapta); leukotriene receptor antagonist – montelukast (Singulair); theophylline]

**AND**

**4** - ONE of the following:

**4.1** BOTH of the following:

**4.1.1** Tezspire will be used to treat eosinophilic asthma

**AND**

**4.1.2** BOTH of the following:

**4.1.2.1** ONE of the following

- Failure to a 4-month trial of an anti-interleukin 5 therapy [e.g., Nucala (mepolizumab), Fasenra (benralizumab)] as confirmed by claims history or submission of medical records
- History of contraindication or intolerance to an anti-interleukin 5 therapy [e.g., Nucala (mepolizumab), Fasenra (benralizumab)] (please specify contraindication or intolerance)

**AND**

**4.1.2.2** ONE of the following:

- Failure to a 4-month trial of Dupixent (dupilumab) as confirmed by claims history or submission of medical records
- History of contraindication or intolerance to Dupixent (dupilumab) (please specify contraindication or intolerance)

**OR**

**4.2** BOTH of the following:

**4.2.1** Tezspire will be used to treat persistent allergic asthma

**AND**

**4.2.2** ONE of the following:

- Failure to a 4-month trial of Xolair (omalizumab) as confirmed by claims history or submission of medical records
- History of intolerance or contraindication to Xolair (omalizumab) (please specify contraindication or intolerance)

**OR**

**4.3** BOTH of the following:

**4.3.1** Tezspire will be used to treat oral corticosteroid dependent asthma

**AND**

**4.3.2** ONE of the following:

- Failure to a 4-month trial of Dupixent (dupilumab) as confirmed by claims history or submission of medical records
- History of intolerance or contraindication to Dupixent (dupilumab) (please specify contraindication or intolerance)

**OR**

**4.4** Patient's asthma is not of the eosinophilic, allergic, or oral corticosteroid dependent phenotype

**AND**

**5** - Patient is NOT receiving Tezspire in combination with any of the following for treatment of the same indication:

- Anti-interleukin 5 therapy [e.g., Cinqair (reslizumab), Fasenra (benralizumab), Nucala (mepolizumab)]
- Anti-IgE therapy [e.g., Xolair (omalizumab)]

- Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]

**AND**

**6** - Prescribed by ONE of the following:

- Allergist
- Immunologist
- Pulmonologist

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                     |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name: Tezspire auto-injector pen                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                     |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Severe Asthma       |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 12 month(s)         |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of positive clinical response to Tezspire therapy as demonstrated by at least ONE of the following:</p> <ul style="list-style-type: none"> <li>• Reduction in the frequency of exacerbations</li> <li>• Decreased utilization of rescue medications</li> <li>• Increase in percent predicted FEV1 (forced expiratory volume in 1 second) from pretreatment baseline</li> <li>• Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.)</li> </ul> <p><b>AND</b></p> <p><b>2</b> - Tezspire is being used in combination with an ICS-containing maintenance medication [e.g., Advair/AirDuo Respiclick (fluticasone propionate/salmeterol), Symbicort (budesonide/formoterol), Breo Ellipta (fluticasone furoate/vilanterol)]</p> <p><b>AND</b></p> |                     |

**3** - Patient is NOT receiving Tezspire in combination with any of the following for treatment of the same indication:

- Anti-interleukin-5 therapy [e.g., Cinqair (reslizumab), Fasenra (benralizumab), Nucala (mepolizumab)]
- Anti-IgE therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin-4 therapy [e.g., Dupixent (dupilumab)]

## 2 . Revision History

| Date      | Notes                                                                                                                                  |
|-----------|----------------------------------------------------------------------------------------------------------------------------------------|
| 9/17/2025 | Added "for treatment of the same indication" to medications patient is not receiving in combination with Tezspire. Added NM formulary. |

Thalomid



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-373190                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Guideline Name</b> | Thalomid                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 9/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                       |                       |
|-----------------------|-----------------------|
| Product Name:Thalomid |                       |
| Diagnosis             | Multiple Myeloma      |
| Approval Length       | 12 month(s)           |
| Therapy Stage         | Initial Authorization |

|                                                                      |                     |
|----------------------------------------------------------------------|---------------------|
| Guideline Type                                                       | Prior Authorization |
| <b>Approval Criteria</b><br><b>1 - Diagnosis of multiple myeloma</b> |                     |

|                                                                                                                                                                                                                                                                                                                                                                                               |                                 |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|
| Product Name:Thalomid                                                                                                                                                                                                                                                                                                                                                                         |                                 |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                     | Erythema Nodosum Leprosum (ENL) |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                               | 12 month(s)                     |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                 | Initial Authorization           |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                | Prior Authorization             |
| <b>Approval Criteria</b><br><b>1 - Diagnosis of moderate to severe erythema nodosum leprosum (ENL)</b><br><br><p style="text-align: center;"><b>AND</b></p> <b>2 - ONE of the following:</b> <ul style="list-style-type: none"> <li>• Used for acute treatment</li> <li>• Used as maintenance therapy for prevention and suppression of cutaneous manifestations of ENL recurrence</li> </ul> |                                 |

|                          |                        |
|--------------------------|------------------------|
| Product Name:Thalomid    |                        |
| Diagnosis                | Castleman Disease (CD) |
| Approval Length          | 12 month(s)            |
| Therapy Stage            | Initial Authorization  |
| Guideline Type           | Prior Authorization    |
| <b>Approval Criteria</b> |                        |

**1 - Diagnosis of Castleman Disease (CD)**

**AND**

**2 - ONE of the following:**

**2.1 NOT used as first line therapy**

**OR**

**2.2 ALL of the following:**

- Therapy is for active idiopathic multicentric CD with no evidence of organ failure
- Used in combination with cyclophosphamide and prednisone
- Patient is human immunodeficiency virus (HIV)-negative
- Patient is human herpesvirus-8 (HHV8)-negative

**Product Name:Thalomid**

|           |                |
|-----------|----------------|
| Diagnosis | Kaposi Sarcoma |
|-----------|----------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

**1 - ONE of the following:**

**1.1 Diagnosis of HIV (human immunodeficiency virus)-negative Kaposi Sarcoma**

**OR**

**1.2 BOTH of the following:**

- Diagnosis of AIDS-related Kaposi Sarcoma

- Patient is currently being treated with antiretroviral therapy (ART) as confirmed by claims history or submission of medical records

**AND**

**2** - NOT used as first line therapy

**AND**

**3** - Patient has immune reconstitution inflammatory syndrome (IRIS)

| Product Name:Thalomid                                                                                                                                              |                                                      |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------|
| Diagnosis                                                                                                                                                          | Langerhans Cell Histiocytosis, Rosai-Dorfman Disease |
| Approval Length                                                                                                                                                    | 12 month(s)                                          |
| Therapy Stage                                                                                                                                                      | Initial Authorization                                |
| Guideline Type                                                                                                                                                     | Prior Authorization                                  |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of Langerhans cell histiocytosis</p> <p><b>OR</b></p> <p><b>2</b> - Diagnosis of Rosai-Dorfman Disease</p> |                                                      |

| Product Name:Thalomid |                           |
|-----------------------|---------------------------|
| Diagnosis             | Pediatric medulloblastoma |
| Approval Length       | 12 month(s)               |
| Therapy Stage         | Initial Authorization     |
| Guideline Type        | Prior Authorization       |



**Approval Criteria**

1 - Diagnosis of pediatric medulloblastoma

**AND**

2 - Disease is recurrent or progressive

**Product Name:Thalomid**

|                 |                                                                                                                                           |
|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------|
| Diagnosis       | Multiple Myeloma, Castleman Disease (CD), Kaposi Sarcoma, Langerhans Cell Histiocytosis, Rosai-Dorfman Disease, Pediatric medulloblastoma |
| Approval Length | 12 month(s)                                                                                                                               |
| Therapy Stage   | Reauthorization                                                                                                                           |
| Guideline Type  | Prior Authorization                                                                                                                       |

**Approval Criteria**

1 - Patient does not show evidence of progressive disease while on Thalomid therapy

**Product Name:Thalomid**

|                 |                           |
|-----------------|---------------------------|
| Diagnosis       | NCCN Recommended Regimens |
| Approval Length | 12 month(s)               |
| Therapy Stage   | Initial Authorization     |
| Guideline Type  | Prior Authorization       |

**Approval Criteria**

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

|                                                                                                     |                                                            |
|-----------------------------------------------------------------------------------------------------|------------------------------------------------------------|
| Product Name:Thalomid                                                                               |                                                            |
| Diagnosis                                                                                           | Erythema Nodosum Leprosum (ENL), NCCN Recommended Regimens |
| Approval Length                                                                                     | 12 month(s)                                                |
| Therapy Stage                                                                                       | Reauthorization                                            |
| Guideline Type                                                                                      | Prior Authorization                                        |
| <b>Approval Criteria</b><br><br>1 - Documentation of positive clinical response to Thalomid therapy |                                                            |

## 2 . Revision History

| Date      | Notes                         |
|-----------|-------------------------------|
| 8/19/2025 | Updated formularies to add IN |

Therapeutic Duplication (Subtype A)



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-423391                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Guideline Name</b> | Therapeutic Duplication (Subtype A)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State Kansas (ACUKS, ACUKSC, ACUKSEC)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State North Carolina (ACUNC)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Texas (ACUTX, ACUTXC, ACUTXEC, ACUTXSK)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 11/1/2025 |
|-----------------|-----------|

## 1 . Criteria

Product Name: Generic arformoterol nebulizer solution, Brand Brovana nebulizer, generic formoterol nebulizer solution, Brand Perforomist nebulizer, Striverdi Respimat, Serevent

Diskus, Incruse Ellipta, Brand Spiriva Handihaler, generic tiotropium, Spiriva Respimat, Tudorza Pressair, generic ipratropium inhalation solution, Atrovent HFA, Anoro Ellipta, Stiolto Respimat, Bevespi Aerosphere, Duaklir Pressair, Breztri Aerosphere, Glyxambi, Steglujan, Qtern, Trijardy XR, Brand Pulmicort suspension, generic budesonide suspension, Victoza, Adlyxin, Trulicity, Bydureon BCise, Byetta, Ozempic, Rybelsus, Januvia, Janumet, Janumet XR, Brand Onglyza, generic saxagliptin, Brand Kombiglyze XR, generic saxagliptin/metformin ER, Tradjenta, Jentadueto, Jentadueto XR, Nesina, alogliptin, Kazano, alogliptin/metformin, Oseni, alogliptin/pioglitazone, Mounjaro, Xultophy, Soliqua, Invokana, brand Farxiga, generic dapagliflozin, Jardiance, Invokamet, Invokamet XR, brand Xigduo XR, generic dapagliflozin/metformin ER, Synjardy, Synjardy XR, Steglatro, Segluromet, Zituvio, Brand Flovent HFA, Fluticasone propionate HFA, Flovent Diskus, Brand Fluticasone propionate Diskus, Brand Pulmicort Flexhaler, Alvesco, ArmonAir Digihaler, Asmanex Twisthaler, Asmanex HFA, Arnuity Ellipta, Qvar RediHaler, Lonhala Magnair, Trelegy Ellipta, Brand Advair Diskus, generic fluticasone propionate/salmeterol diskus (generic Advair Diskus), generic Wixela Inhub (generic Advair Diskus), AirDuo Respiclick, fluticasone/salmeterol (authorized generic of AirDuo), Brand Advair HFA, Brand Fluticasone/salmeterol HFA, Brand Symbicort, generic budesonide/formoterol, Breyna, AirDuo Digihaler, Dulera, Breo Ellipta, Brand fluticasone/vilanterol Ellipta, Basaglar Tempo pen, Basaglar Kwikpen, Insulin Glargine Solostar, Lantus Solostar, Toujeo Solostar, Toujeo Max Solostar, Semglee Pen Injector, Insulin Glargine-YFGN pen, Lantus vial, Insulin Glargine vial, Semglee vial, Insulin Glargine-YFGN vial, Levemir vial, Levemir Flextouch, Levemir Flexpen, Tresiba vial, Insulin Degludec vial, Tresiba Flextouch, Insulin Degludec Flextouch, Rezvoglar, Baclofen tabs, generic baclofen suspension, Brand Fleqsuvy, Brand Ozobax DS, brand Ozobax, Brand Baclofen solution, brand Lioresal intrathecal, generic baclofen intrathecal, brand Gablofen intrathecal, baclofen intrathecal solution, Lyvispah, generic carisoprodol tab, brand Soma, brand Vanadom tab, generic chlorzoxazone, brand Lorzone, generic cyclobenzaprine, brand Fexmid, generic cyclobenzaprine ER, brand Amrix, metaxalone, methocarbamol, orphenadrine CR/ER, generic tizanidine caps/tabs, brand Zanaflex caps/tabs, brand Dantrium, generic dantrolene, brand Norgesic, generic orphenadrine/aspirin/cafeine, norgesic forte, orphengesic forte, Brand Neurontin caps/tabs/soln, generic gabapentin caps/tabs/soln, gabapentin tinytabs, brand Lyrica caps/soln, generic pregabalin caps/soln, brand Gralise, brand Lyrica CR, generic pregabalin ER, Horizant, Zorvolex, brand Zipsor, generic diclofenac caps, brand Lofena, generic diclofenac tabs, diclofenac DR/ER, brand Cambia, generic diclofenac packet (migraine), etodolac cap, brand Lodine, generic etodolac tab, etodolac ER, brand Nalfon caps/tabs, generic fenoprofen caps/tabs, flurbiprofen, ibuprofen caps/tabs/chewable (includes All Manufactures), Brand Advil, ibuprofen suspension (40 mg/ml & 100 mg/5ml), indomethacin caps, indomethacin ER/SR caps, indocin susp, indocin suppository, indomethacin suppository, ketoprofen cap, ketoprofen ER cap, ketorolac tabs, meclofenamate cap, mefenamic acid, meloxicam cap/tab, brand Relafen DS, generic nabumetone, generic naproxen tab/susp/caps (includes All Manufactures), brand naprosyn tab/susp, brand Aleve, brand Anaprox DS, brand EC-Naprosyn, generic naproxen DR, generic EC-naproxen, brand Naprelan, generic naproxen CR/ER, Brand Daypro, generic oxaprozin, brand Feldene, generic piroxicam, sulindac, tolmetin, brand Celebrex, generic celecoxib, Elyxyb, brand Arthrotec, generic diclofenac sodium/misoprostol, brand Duexis, generic ibuprofen/famotidine, brand Vimovo, generic naproxen/esomeprazole, brand Advil PM, generic ibuprofen/diphenhydramine, brand Aleve PM, generic naproxen/diphenhydramine, hydrocodone/ibuprofen, brand Treximet, generic sumatriptan/naproxen, Motrin Dual Action/Tylenol, Advil Dual Action/acetaminophen, acetaminophen/ibuprofen, Naproxen/capsaicin cream (Naprotin), Inpefa, Saxenda, Wegovy, Brand Brenzavvy, Brand Bexagliflozin, Zepbound, Coxanto, Jantoven, warfarin tabs, Pradaxa,

generic dabigatran, Eliquis, Savaysa, Xarelto, Brand Lunesta, generic eszopiclone, zaleplon, Zolpidem, Brand Ambien, generic zolpidem, Brand Ambien CR, generic zolpidem CR. Edluar, Zolpimist, Brand Rozerem, generic ramelteon, Brand Silenor, generic doxepin (sleep) 3mg and 6 mg tabs, Belsomra, Dayvigo, Quviviq, Brand Precedex, generic dexmedetomidine, Dexmedetomidine, Igalmi, Brand Hetlioz, generic tasimelteon, Hetlioz LQ, Brand Restoril, generic temazepam, Brand Halcion, generic triazolam, Brand Doral, generic quazepam, flurazepam, estazolam, Zituvimet, Sitagliptin/metformin, Brand Tanlor, Dolobid, generic diflunisal, Zituvimet XR, Tresni, Fenopron, Gabarone, Addaprin, Symbravo, Exenatide, Brynovin

|                 |                              |
|-----------------|------------------------------|
| Diagnosis       | DUR: Therapeutic Duplication |
| Approval Length | 12 month(s)                  |
| Guideline Type  | Administrative               |

### Approval Criteria

**1** - The requested medication will be used exclusively, and the previously prescribed medication will be discontinued

**OR**

**2** - All of the following:

**2.1** The requested medication combination is supported by information from ONE of the following appropriate compendia of current literature:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopoeia-National Formulary (USP-NF)

**AND**

**2.2** The drug combination is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plan's program

**AND**

**2.3** The provider attests that they are aware that the patient is using duplicate therapy

**AND**

**2.4** Special clinical circumstances exist that necessitate the need for duplicate therapy (document special circumstances)

**AND**

**2.5** Provider attests that the necessity for continued concomitant therapy and safety will be periodically assessed

## 2 . Revision History

| Date       | Notes           |
|------------|-----------------|
| 10/22/2025 | Added Brynovin. |

Therapeutic Duplication (Subtype B)



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-422538                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Guideline Name</b> | Therapeutic Duplication (Subtype B)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Arizona (ACUAZ, ACUAZEC)</li> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State Kansas (ACUKS, ACUKSC, ACUKSEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State North Carolina (ACUNC)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Washington (ACUWA, ACUWAAHE, ACUWAC)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 11/1/2025 |
|-----------------|-----------|

## 1 . Criteria

Product Name:(All formulations/packaging, except for Entyvio) Entyvio Pen, Stelara, Cimzia, Abrilada, Humira, Amjevita, Idacio, Hulio, Cyltezo, Yusimry, Yuflyma, Hadlima, Hyrimoz, Adalimumab (all products), Simponi, Enbrel, Actemra, Cosentyx, Ilaris, Kineret, Kevzara, Taltz, Tremfya, Oencia, Xeljanz, Xeljanz XR, Xeljanz Solution, Siliq, Otezla, Olumiant, Ilumya, Skyrizi, Rinvoq, Sotyktu, Cibinqo, Adbry, Dupixent, brand Copaxone, generic glatiramer acetate, generic glatopa, Mavenclad, Rebif, Avonex, Betaseron, Extavia, brand Aubagio, generic teriflunomide, Plegridy, Lemtrada, Tysabri, Ocrevus, brand Tecfidera, generic dimethyl fumarate, Vumerity, brand Gilenya, generic fingolimod, Tascenso ODT, Zeposia, Mayzent, Bafiertam, Kesimpta, Ponvory, Xolair, Fasenra, Nucala, Cinqair, Tezspire, Velsipity, Bimzelx, Omvoh, Zymfentra, Simlandi, Spevigo, Tyenne, Rinvoq LQ, Nemludio, Ebglyss, Wezlana, Steqeyma, Yesintek, Pyzchiva, Otulfi, Selarsdi, Imuldosa, Ustekinumab (all products), Leqselvi, Litfulo, Avtozma, Otezla XR

|                                                                                                                                                             |                              |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|
| Diagnosis                                                                                                                                                   | DUR: Therapeutic Duplication |
| Approval Length                                                                                                                                             | 12 month(s)                  |
| Guideline Type                                                                                                                                              | Administrative               |
| <p><b>Approval Criteria</b></p> <p>1 - The requested medication will be used exclusively, and the previously prescribed medication will be discontinued</p> |                              |

## 2 . Revision History

| Date       | Notes                          |
|------------|--------------------------------|
| 10/21/2025 | Removed MI. Updated drug list. |



Tibsovo



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-208199                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Guideline Name</b> | Tibsovo                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 4/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                      |                              |
|----------------------|------------------------------|
| Product Name:Tibsovo |                              |
| Diagnosis            | Acute Myeloid Leukemia (AML) |
| Approval Length      | 12 month(s)                  |
| Therapy Stage        | Initial Authorization        |

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Prior Authorization |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1 - Diagnosis of acute myeloid leukemia (AML)</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>2 - AML is IDH1 (isocitrate dehydrogenase 1) mutation-positive</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>3 - ONE of the following:</b></p> <p><b>3.1 Disease is relapsed or refractory</b></p> <p style="text-align: center;"><b>OR</b></p> <p><b>3.2 BOTH of the following:</b></p> <p><b>3.2.1 New diagnosis of AML</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>3.2.2 ONE of the following:</b></p> <ul style="list-style-type: none"> <li>• Patient is 75 years of age or older</li> <li>• Patient has comorbidities that preclude the use of intensive induction chemotherapy</li> <li>• Patient is 60 years of age or older AND not a candidate for or declines intensive induction therapy</li> <li>• Patient is 60 years of age or older AND receiving post-induction therapy following response to previous lower intensity therapy</li> </ul> |                     |

|                       |             |
|-----------------------|-------------|
| Product Name: Tibsovo |             |
| Diagnosis             | Bone Cancer |

|                                                                                                                                                                                                                                                                                                                                                                                                     |                       |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                     | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                       | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                      | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of chondrosarcoma</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Susceptible IDH1 (isocitrate dehydrogenase 1) mutation-positive</p> <p style="text-align: center;"><b>AND</b></p> <p>3 - Disease is ONE of the following:</p> <ul style="list-style-type: none"> <li>• Conventional (grades 1-3)</li> <li>• Dedifferentiated</li> </ul> |                       |

|                                                                                                                                                                                                     |                       |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name: Tibsovo                                                                                                                                                                               |                       |
| Diagnosis                                                                                                                                                                                           | Biliary Tract Cancer  |
| Approval Length                                                                                                                                                                                     | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                       | Initial Authorization |
| Guideline Type                                                                                                                                                                                      | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of cholangiocarcinoma</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Susceptible IDH1 (isocitrate dehydrogenase 1) mutation-positive</p> |                       |

**AND**

**3** - Disease is ONE of the following:

- Locally advanced
- Unresectable
- Metastatic

**AND**

**4** - Disease has progressed on or after systemic treatment

|                                                                                                                                                                                                                                                                                                                                                                                       |                       |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name: Tibsovo                                                                                                                                                                                                                                                                                                                                                                 |                       |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                             | Oligodendroglioma     |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                       | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                         | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                        | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of oligodendroglioma</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Disease is recurrent or progressive</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Presence of BOTH of the following:</p> <ul style="list-style-type: none"> <li>• IDH1 mutation</li> <li>• 1p19q codeletion</li> </ul> |                       |

**AND**

**4** - Disease is WHO grade 2 or 3

Product Name: Tibsovo

|           |             |
|-----------|-------------|
| Diagnosis | Astrocytoma |
|-----------|-------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

**1** - Diagnosis of astrocytoma

**AND**

**2** - Disease is recurrent or progressive

**AND**

**3** - Presence of IDH1 mutation

**AND**

**4** - Disease is WHO grade 2, 3, or 4

Product Name: Tibsovo

|           |                                |
|-----------|--------------------------------|
| Diagnosis | Myelodysplastic Syndrome (MDS) |
|-----------|--------------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

**1** - Diagnosis of myelodysplastic syndrome (MDS)

**AND**

**2** - Disease is relapsed or refractory

**AND**

**3** - Presence of IDH1 mutation

**Product Name:**Tibsovo

|                 |                                                                                                                                 |
|-----------------|---------------------------------------------------------------------------------------------------------------------------------|
| Diagnosis       | Acute Myeloid Leukemia (AML), Bone Cancer, Biliary Tract Cancer, Oligodendroglioma, Astrocytoma, Myelodysplastic syndrome (MDS) |
| Approval Length | 12 month(s)                                                                                                                     |
| Therapy Stage   | Reauthorization                                                                                                                 |
| Guideline Type  | Prior Authorization                                                                                                             |

**Approval Criteria**

**1** - Patient does not show evidence of progressive disease while on Tibsovo therapy

**Product Name:**Tibsovo

|                 |                           |
|-----------------|---------------------------|
| Diagnosis       | NCCN Recommended Regimens |
| Approval Length | 12 month(s)               |
| Therapy Stage   | Initial Authorization     |
| Guideline Type  | Prior Authorization       |

**Approval Criteria**

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Tibsovo

|           |                           |
|-----------|---------------------------|
| Diagnosis | NCCN Recommended Regimens |
|-----------|---------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                 |
|---------------|-----------------|
| Therapy Stage | Reauthorization |
|---------------|-----------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

1 - Documentation of positive clinical response to Tibsovo therapy

## 2 . Revision History

| Date     | Notes                                                                       |
|----------|-----------------------------------------------------------------------------|
| 3/5/2025 | Updated formularies. Updated criteria for oligodendroglioma and astrocytoma |

## Tobramycin Inhalation



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-441208                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Guideline Name</b> | Tobramycin Inhalation                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 12/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                                                                     |                     |
|---------------------------------------------------------------------|---------------------|
| Product Name:Generic tobramycin 300 mg/5mL nebu soln (generic TOBI) |                     |
| Approval Length                                                     | 12 month(s)         |
| Guideline Type                                                      | Prior Authorization |
| Approval Criteria                                                   |                     |



**1 - Diagnosis of cystic fibrosis (CF)**

**OR**

**2 - BOTH of the following:**

**2.1** Diagnosis of noncystic fibrosis bronchiectasis

**AND**

**2.2** ONE of the following:

**2.2.1** Three or more exacerbations per year

**OR**

**2.2.2** Two or more exacerbations requiring hospitalization per year

Product Name: Kitabis Pak, Brand Tobi nebu soln, Tobi Podhaler, Brand Bethkis, generic tobramycin 300 mg/4mL nebu soln (generic Bethkis), Brand Tobramycin solution for inhalation

|                 |                       |
|-----------------|-----------------------|
| Approval Length | 12 month(s)           |
| Therapy Stage   | Initial Authorization |
| Guideline Type  | Prior Authorization   |

**Approval Criteria**

**1 - ONE of the following:**

**1.1** Diagnosis of cystic fibrosis (CF)

**OR**

**1.2** BOTH of the following:

**1.2.1** Diagnosis of noncystic fibrosis bronchiectasis

**AND**

**1.2.2** ONE of the following:

**1.2.2.1** Three or more exacerbations per year

**OR**

**1.2.2.2** Two or more exacerbations requiring hospitalization per year

**AND**

**2** - Lung infection with positive culture demonstrating *Pseudomonas aeruginosa* infection

**AND**

**3** - ONE of the following:

**3.1** Failure to generic tobramycin 300 mg/5mL solution for inhalation (generic TOBI) as confirmed by claims history or submission of medical records

**OR**

**3.2** History of contraindication or intolerance to generic tobramycin 300 mg/5mL solution for inhalation (generic TOBI) (please specify contraindication or intolerance)

|                                                                                                                                                                                   |                     |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Kitabis Pak, Brand Tobi nebu soln, Tobi Podhaler, Brand Bethkis, generic tobramycin 300 mg/4mL nebu soln (generic Bethkis), Brand Tobramycin solution for inhalation |                     |
| Approval Length                                                                                                                                                                   | 12 month(s)         |
| Therapy Stage                                                                                                                                                                     | Reauthorization     |
| Guideline Type                                                                                                                                                                    | Prior Authorization |

**Approval Criteria**

1 - Documentation of positive clinical response to therapy

**2 . Revision History**

| Date      | Notes                                                                                         |
|-----------|-----------------------------------------------------------------------------------------------|
| 11/6/2025 | Updated GPI list/product name list to clarify MSC M tobramycin is no n-preferred. Removed IN. |

Tocilizumab



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-238227                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Guideline Name</b> | Tocilizumab                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 6/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                                                                 |                           |
|-----------------------------------------------------------------|---------------------------|
| Product Name:Actemra subcutaneous, Tyenne subcutaneous, Avtozma |                           |
| Diagnosis                                                       | Rheumatoid Arthritis (RA) |
| Approval Length                                                 | 12 month(s)               |
| Therapy Stage                                                   | Initial Authorization     |
| Guideline Type                                                  | Prior Authorization       |

## **Approval Criteria**

**1** - ALL of the following:

**1.1** Diagnosis of moderately to severely active rheumatoid arthritis (RA)

**AND**

**1.2** ONE of the following:

**1.2.1** Failure to a 3 month trial of ONE non-biologic disease modifying anti-rheumatic drug (DMARD) [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine] at maximally indicated doses confirmed by claims history or submitted medical records

**OR**

**1.2.2** History of intolerance or contraindication to ONE non-biologic DMARD [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine] (please specify intolerance or contraindication)

**OR**

**1.2.3** Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of rheumatoid arthritis as confirmed by claims history or submission of medical records [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orenzia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

**AND**

**1.3** ONE of the following:

**1.3.1** Failure of ONE of the preferred adalimumab products confirmed by claims history or submitted medical records

**OR**

**1.3.2** History of intolerance or contraindication to ALL preferred adalimumab products (please specify intolerance or contraindication)

**AND**

**1.4** If the request is for a non-preferred tocilizumab product, the prescriber has given a clinical reason or special circumstance why the patient is unable to use the preferred tocilizumab products (please document reason/special circumstances)

**AND**

**1.5** Patient is NOT receiving tocilizumab in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

**AND**

**1.6** Prescribed by or in consultation with a rheumatologist

**AND**

**1.7** If the request is for BRAND Actemra, one of the following:

**1.7.1** Submission of medical records confirming patient allergy or intolerance to at least one preferred tocilizumab biosimilar's inactive ingredients

**OR**

**1.7.2** Both of the following:

- Submission of medical records confirming patient has previously been successfully treated with brand Actemra
- Submission of medical records confirming patient has tried at least one preferred tocilizumab biosimilar for 6-8 weeks per product and saw a decrease in effectiveness

**OR**

**2 - ALL of the following:**

**2.1** Patient is currently on tocilizumab therapy as confirmed by claims history or submitted medical records

**AND**

**2.2** Diagnosis of moderately to severely active RA

**AND**

**2.3** Patient is NOT receiving tocilizumab in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

**AND**

**2.4** If the request is for a non-preferred tocilizumab product, the prescriber has given a clinical reason or special circumstance why the patient is unable to use the preferred tocilizumab products (please document reason/special circumstances)

**AND**

**2.5** Prescribed by or in consultation with a rheumatologist

**AND**

**2.6** If the request is for BRAND Actemra, one of the following:

**2.6.1** Submission of medical records confirming patient allergy or intolerance to at least one preferred tocilizumab biosimilar's inactive ingredients

**OR**

**2.6.2** Both of the following:

- Submission of medical records confirming patient has previously been successfully treated with brand Actemra
- Submission of medical records confirming patient has tried at least one preferred tocilizumab biosimilar for 6-8 weeks per product and saw a decrease in effectiveness

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                            |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|
| Product Name:Actemra subcutaneous, Tyenne subcutaneous, Avtozma                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                            |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Giant Cell Arteritis (GCA) |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 12 month(s)                |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Initial Authorization      |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Prior Authorization        |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of giant cell arteritis</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - ONE of the following:</p> <p><b>2.1</b> Failure to ONE glucocorticoid (e.g., prednisone) confirmed by claims history or submitted medical records</p> <p style="text-align: center;"><b>OR</b></p> <p><b>2.2</b> History of intolerance or contraindication to ALL glucocorticoids (e.g., prednisone) (please specify intolerance or contraindication)</p> <p style="text-align: center;"><b>OR</b></p> |                            |



**2.3** Patient is currently on tocilizumab therapy as confirmed by claims history or submitted medical records

**AND**

**3** - If the request is for a non-preferred tocilizumab product, the prescriber has given a clinical reason or special circumstance why the patient is unable to use the preferred tocilizumab products (please document reason/special circumstances)

**AND**

**4** - Patient is NOT receiving tocilizumab in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

**AND**

**5** - Prescribed by or in consultation with a rheumatologist

**AND**

**6** - If the request is for BRAND Actemra, one of the following:

**6.1** Submission of medical records confirming patient allergy or intolerance to at least one preferred tocilizumab biosimilar's inactive ingredients

**OR**

**6.2** Both of the following:

- Submission of medical records confirming patient has previously been successfully treated with brand Actemra
- Submission of medical records confirming patient has tried at least one preferred tocilizumab biosimilar for 6-8 weeks per product and saw a decrease in effectiveness

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                    |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------|
| Product Name:Actemra subcutaneous, Tyenne subcutaneous, Avtozma                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                    |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Polyarticular Juvenile Idiopathic Arthritis (PJIA) |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 12 month(s)                                        |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Initial Authorization                              |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Prior Authorization                                |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis (PJIA)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - ONE of the following:</p> <p><b>2.1</b> Failure to ONE of the preferred adalimumab products confirmed by claims history or submitted medical records</p> <p style="text-align: center;"><b>OR</b></p> <p><b>2.2</b> History of intolerance or contraindication to ALL of the preferred adalimumab products (please specify intolerance or contraindication)</p> <p style="text-align: center;"><b>OR</b></p> <p><b>2.3</b> Patient is currently on tocilizumab therapy as confirmed by claims history or submitted medical records</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - If the request is for a non-preferred tocilizumab product, the prescriber has given a clinical reason or special circumstance why the patient is unable to use the preferred tocilizumab products (please document reason/special circumstances)</p> <p style="text-align: center;"><b>AND</b></p> |                                                    |

**4** - Patient is NOT receiving tocilizumab in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

**AND**

**5** - Prescribed by or in consultation with a rheumatologist

**AND**

**6** - If the request is for BRAND Actemra, one of the following:

**6.1** Submission of medical records confirming patient allergy or intolerance to at least one preferred tocilizumab biosimilar's inactive ingredients

**OR**

**6.2** Both of the following:

- Submission of medical records confirming patient has previously been successfully treated with brand Actemra
- Submission of medical records confirming patient has tried at least one preferred tocilizumab biosimilar for 6-8 weeks per product and saw a decrease in effectiveness

|                                                                                                                     |                                               |
|---------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|
| Product Name:Actemra subcutaneous, Tyenne subcutaneous, Avtozma                                                     |                                               |
| Diagnosis                                                                                                           | Systemic Juvenile Idiopathic Arthritis (SJIA) |
| Approval Length                                                                                                     | 12 month(s)                                   |
| Therapy Stage                                                                                                       | Initial Authorization                         |
| Guideline Type                                                                                                      | Prior Authorization                           |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of active systemic juvenile idiopathic arthritis (SJIA)</p> |                                               |

**AND**

**2** - Patient is NOT receiving tocilizumab in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

**AND**

**3** - If the request is for a non-preferred tocilizumab product, the prescriber has given a clinical reason or special circumstance why the patient is unable to use the preferred tocilizumab products (please document reason/special circumstances)

**AND**

**4** - Prescribed by or in consultation with a rheumatologist

**AND**

**5** - If the request is for BRAND Actemra, one of the following:

**5.1** Submission of medical records confirming patient allergy or intolerance to at least one preferred tocilizumab biosimilar's inactive ingredients

**OR**

**5.2** Both of the following:

- Submission of medical records confirming patient has previously been successfully treated with brand Actemra
- Submission of medical records confirming patient has tried at least one preferred tocilizumab biosimilar for 6-8 weeks per product and saw a decrease in effectiveness

|                                                                 |                                                                   |
|-----------------------------------------------------------------|-------------------------------------------------------------------|
| Product Name:Actemra subcutaneous, Tyenne subcutaneous, Avtozma |                                                                   |
| Diagnosis                                                       | Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD) |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                       |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD) as documented by ALL of the following:</p> <p><b>1.1</b> ONE of the following:</p> <p><b>1.1.1</b> Skin thickening of the fingers of both hands extending proximal to the metacarpophalangeal joints</p> <p style="text-align: center;"><b>OR</b></p> <p><b>1.1.2</b> At least TWO of the following:</p> <ul style="list-style-type: none"> <li>• Skin thickening of the fingers (e.g., puffy fingers, sclerodactyly of the fingers)</li> <li>• Fingertip lesions (e.g., digital tip ulcers, fingertip pitting scars)</li> <li>• Telangiectasia</li> <li>• Abnormal nailfold capillaries</li> <li>• Pulmonary arterial hypertension</li> <li>• Raynaud's phenomenon</li> <li>• SSc-related autoantibodies (e.g., anticentromere, anti-topoisomerase I, anti-RNA polymerase III)</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>1.2</b> Presence of interstitial lung disease as determined by finding evidence of pulmonary fibrosis on HRCT (high-resolution computed tomography), involving at least 10% of the lungs</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Patient is NOT receiving tocilizumab in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]</p> |                       |

**AND**

**3** - If the request is for a non-preferred tocilizumab product, the prescriber has given a clinical reason or special circumstance why the patient is unable to use the preferred tocilizumab products (please document reason/special circumstances)

**AND**

**4** - Prescribed by or in consultation with a pulmonologist

**AND**

**5** - If the request is for BRAND Actemra, one of the following:

**5.1** Submission of medical records confirming patient allergy or intolerance to at least one preferred tocilizumab biosimilar's inactive ingredients

**OR**

**5.2** Both of the following:

- Submission of medical records confirming patient has previously been successfully treated with brand Actemra
- Submission of medical records confirming patient has tried at least one preferred tocilizumab biosimilar for 6-8 weeks per product and saw a decrease in effectiveness

|                                                                 |                              |
|-----------------------------------------------------------------|------------------------------|
| Product Name:Actemra subcutaneous, Tyenne subcutaneous, Avtozma |                              |
| Diagnosis                                                       | RA, GCA, PJIA, SJIA, SSc-ILD |
| Approval Length                                                 | 12 month(s)                  |
| Therapy Stage                                                   | Reauthorization              |
| Guideline Type                                                  | Prior Authorization          |
|                                                                 |                              |

## Approval Criteria

**1** - Documentation of positive clinical response to tocilizumab therapy

**AND**

**2** - Patient is NOT receiving tocilizumab in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]\*

**AND**

**3** - If the request is for a non-preferred tocilizumab product, the prescriber has given a clinical reason or special circumstance why the patient is unable to use the preferred tocilizumab products (please document reason/special circumstances)

**AND**

**4** - If the request is for BRAND Actemra, one of the following:

**4.1** Submission of medical records confirming patient allergy or intolerance to at least one preferred tocilizumab biosimilar's inactive ingredients

**OR**

**4.2** Both of the following:

- Submission of medical records confirming patient has previously been successfully treated with brand Actemra
- Submission of medical records confirming patient has tried at least one preferred tocilizumab biosimilar for 6-8 weeks per product and saw a decrease in effectiveness

Notes

\* Examples of drug(s) may not be applicable based on the requested indication.

## 2 . Background

## Benefit/Coverage/Program Information

### PDL Links

CO: <https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html>

HI: <https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html>

MD: <https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-cp-pharmacy.html>

NJ: <https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html>

NY: <https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html>

PA: <https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP>

RI: <https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html>

NM: <https://www.uhcprovider.com/en/health-plans-by-state/new-mexico-health-plans/nm-comm-plan-home/nm-cp-pharmacy.html>

## 3 . Revision History

| Date      | Notes         |
|-----------|---------------|
| 4/15/2025 | Added Avtozma |



Tolvaptan



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-421303                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Guideline Name</b> | Tolvaptan                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Pennsylvania (ACUPA)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 11/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                                                                             |                                                      |
|-----------------------------------------------------------------------------|------------------------------------------------------|
| Product Name: Brand Jynarque, generic tolvaptan tab, generic tolvaptan pack |                                                      |
| Diagnosis                                                                   | Autosomal dominant polycystic kidney disease (ADPKD) |
| Approval Length                                                             | 12 month(s)                                          |

|                                                                                                       |                                               |
|-------------------------------------------------------------------------------------------------------|-----------------------------------------------|
| Therapy Stage                                                                                         | Initial Authorization                         |
| Guideline Type                                                                                        | Prior Authorization                           |
| <b>Approval Criteria</b><br><br>1 - Diagnosis of autosomal dominant polycystic kidney disease (ADPKD) |                                               |
| Notes                                                                                                 | This criteria comes from the Jynarque policy. |

|                                                                                            |                                                      |
|--------------------------------------------------------------------------------------------|------------------------------------------------------|
| Product Name:Brand Jynarque, generic tolvaptan tab, generic tolvaptan pack                 |                                                      |
| Diagnosis                                                                                  | Autosomal dominant polycystic kidney disease (ADPKD) |
| Approval Length                                                                            | 12 month(s)                                          |
| Therapy Stage                                                                              | Reauthorization                                      |
| Guideline Type                                                                             | Prior Authorization                                  |
| <b>Approval Criteria</b><br><br>1 - Documentation of positive clinical response to therapy |                                                      |
| Notes                                                                                      | This criteria comes from the Jynarque policy.        |

|                                                                                                                                                                                                                                                   |                                        |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------|
| Product Name:Brand Samsca, generic tolvaptan tab                                                                                                                                                                                                  |                                        |
| Diagnosis                                                                                                                                                                                                                                         | Hypervolemic or Euvolemic Hyponatremia |
| Approval Length                                                                                                                                                                                                                                   | 30 Day(s)                              |
| Guideline Type                                                                                                                                                                                                                                    | Prior Authorization                    |
| <b>Approval Criteria</b><br><br>1 - ONE of the following: <ul style="list-style-type: none"> <li>• Diagnosis of clinically significant euvolemic hyponatremia</li> <li>• Diagnosis of clinically significant hypervolemic hyponatremia</li> </ul> |                                        |

|                                                                                                  |                                             |
|--------------------------------------------------------------------------------------------------|---------------------------------------------|
| <b>AND</b>                                                                                       |                                             |
| <b>2</b> - Patient has not responded to fluid restriction                                        |                                             |
| <b>AND</b>                                                                                       |                                             |
| <b>3</b> - Treatment has been initiated or re-initiated in a hospital setting prior to discharge |                                             |
| Notes                                                                                            | This criteria comes from the Samsca policy. |

## 2 . Revision History

| Date       | Notes                                                                                       |
|------------|---------------------------------------------------------------------------------------------|
| 10/21/2025 | Updated formularies. Combined Jynarque and Samsca GLs because they share GPIs. Updated GPIs |

Topical NSAIDs



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-404202                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Guideline Name</b> | Topical NSAIDs                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 10/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                                                               |                     |
|---------------------------------------------------------------|---------------------|
| Product Name: Brand Diclofenac Epolamine patch, Flector patch |                     |
| Approval Length                                               | 12 month(s)         |
| Guideline Type                                                | Prior Authorization |
| Approval Criteria                                             |                     |

**1 - Diagnosis of acute pain due to minor strains, sprains, or contusions**

**AND**

**2 - The patient did not receive adequate pain relief when treated with at least TWO preferred\* non-steroidal anti-inflammatory drugs (NSAIDs), one of which must be celecoxib (generic for Celebrex), as confirmed by claims history or submitted medical records. An inadequate response to treatment is defined as pain and/or inflammatory symptoms not resolved after 14 days of therapy**

**AND**

**3 - ONE of the following:**

**3.1 Failure to ONE of the following, as confirmed by claims history or submission of medical records:**

- diclofenac topical gel 1% [Rx (prescription) formulation]
- diclofenac topical gel 1% [OTC (over-the-counter) formulation]

**OR**

**3.2 History of intolerance or contraindication to BOTH of the following (please provide intolerance or contraindication):**

- diclofenac topical gel 1% (Rx formulation)
- diclofenac topical gel 1% (OTC formulation)

Notes

\*PDL links are listed in Background.

Product Name: Brand Pennsaid, generic diclofenac sodium soln 2%, diclofenac sodium soln 1.5%

Approval Length 12 month(s)

Guideline Type Prior Authorization

**Approval Criteria**

**1 - Diagnosis of pain due to osteoarthritis of the knee(s)**

**AND**

**2 - The patient did not receive adequate pain relief when treated with at least TWO preferred\* non-steroidal anti-inflammatory drugs (NSAIDs), one of which must be celecoxib (generic for Celebrex), as confirmed by claims history or submitted medical records. An inadequate response to treatment is defined as pain and/or inflammatory symptoms not resolved after 14 days of therapy**

**AND**

**3 - ONE of the following:**

**3.1 If the request is for Pennsaid (diclofenac sodium soln 2%), ONE of the following:**

**3.1.1 Failure to BOTH of the following, as confirmed by claims history or submission of medical records:**

- diclofenac topical gel 1% [Rx (prescription) or OTC (over-the-counter) formulation] (generic for Voltaren)
- diclofenac 1.5% topical solution

**OR**

**3.1.2 History of intolerance or contraindication to BOTH of the following (please provide intolerance or contraindication):**

- diclofenac topical gel 1% (Rx or OTC formulation) (generic for Voltaren)
- diclofenac 1.5% topical solution

**OR**

**3.2 If the request is for diclofenac topical solution 1.5%, ONE of the following:**

**3.2.1 Failure to ONE of the following, as confirmed by claims history or submission of medical records:**

- diclofenac topical gel 1% (Rx formulation) (generic for Voltaren)

- diclofenac topical gel 1% (OTC formulation) (generic for Voltaren)

**OR**

**3.2.2** History of intolerance or contraindication to BOTH of the following (please provide intolerance or contraindication):

- diclofenac topical gel 1% (Rx formulation) (generic for Voltaren)
- diclofenac topical gel 1% (OTC formulation) (generic for Voltaren)

Notes

\*PDL links are listed in Background.

Product Name: Brand Voltaren (Rx and OTC formulations)

Approval Length

12 month(s)

Guideline Type

Prior Authorization

### Approval Criteria

**1** - Diagnosis of pain due to osteoarthritis of joints amenable to topical treatment, including but not limited to the hands, knees, ankles, elbows, feet, and wrists

**AND**

**2** - ONE of the following:

**2.1** If the request is for Brand Voltaren Rx (prescription) formulation, BOTH of the following:

**2.1.1** The patient did not receive adequate pain relief when treated with at least TWO preferred\* non-steroidal anti-inflammatory drugs (NSAIDs), one of which must be celecoxib (generic for Celebrex), as confirmed by claims history or submitted medical records. An inadequate response to treatment is defined as pain and/or inflammatory symptoms not resolved after 14 days of therapy

**AND**

**2.1.2** ONE of the following:

**2.1.2.1** Failure to BOTH of the following, as confirmed by claims history or submission of medical records:

- diclofenac topical gel 1% [Rx or OTC (over-the-counter) formulation] (generic Voltaren)
- Brand Voltaren topical gel 1% (OTC formulation)

**OR**

**2.1.2.2** History of intolerance or contraindication to BOTH of the following (please provide intolerance or contraindication):

- diclofenac topical gel 1% (Rx or OTC formulation) (generic Voltaren)
- Brand Voltaren topical gel 1% (OTC formulation)

**OR**

**2.2** If the request is for Brand Voltaren OTC formulation, ONE of the following:

**2.2.1** Failure to ONE of the following, as confirmed by claims history or submission of medical records:

- diclofenac topical gel 1% (Rx formulation) (generic Voltaren)
- diclofenac topical gel 1% (OTC formulation) (generic Voltaren)

**OR**

**2.2.2** History of intolerance or contraindication to BOTH of the following (please provide intolerance or contraindication):

- diclofenac topical gel 1% (Rx formulation) (generic Voltaren)
- diclofenac topical gel 1% (OTC formulation) (generic Voltaren)

Notes

\*PDL links are listed in Background.

## 2 . Background

**Benefit/Coverage/Program Information**



## PDL Links

CO: <https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html>

HI: <https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html>

MD: <https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-cp-pharmacy.html>

NJ: <https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html>

NY/NY EPP: <https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html>

PA CHIP: <https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP>

RI: <https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html>

NM: <https://www.uhcprovider.com/en/health-plans-by-state/new-mexico-health-plans/nm-comm-plan-home/nm-cp-pharmacy.html>

## 3 . Revision History

| Date      | Notes                                                                                                                                                                                                            |
|-----------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 9/25/2025 | Combined formularies. Added PDL link for NM in background section . Minor update to product name sections, where applicable. Minor updates to criteria throughout guideline, with no changes to clinical intent. |

Topical Retinoid Products



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-161604                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Guideline Name</b> | Topical Retinoid Products                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 1/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                                                                                                                                                                                                                                                                                                                                                                           |                     |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:generic tretinoin microsphere, Retin-A Micro, Brand Differin cream, generic adapalene cream, Differin gel (Rx only)/lotion, adapalene gel/soln/pads, Fabior, tazarotene foam, Tazorac, generic tazarotene, adapalene/benzoyl peroxide, Brand Epiduo, Brand Epiduo Forte, Brand Atralin, generic tretinoin gel, Avita, Brand Retin-A, Altreno, Akliel, Arazlo |                     |
| Approval Length                                                                                                                                                                                                                                                                                                                                                           | 12 month(s)         |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                            | Prior Authorization |

### **Approval Criteria**

**1** - The patient has a non-cosmetic medical condition (e.g., acne vulgaris, psoriasis, precancerous skin lesions) (See Table 1 in Background for additional list of non-cosmetic medical conditions)

**AND**

**2** - Medication is not being requested solely for cosmetic purposes (e.g., photo-aging, wrinkling, hyperpigmentation, sun damage, melasma) (See Table 1 in Background for additional list of non-cosmetic medical conditions)

**AND**

**3** - ONE of the following:

**3.1** BOTH of the following:

**3.1.1** Patient has a diagnosis of acne vulgaris

**AND**

**3.1.2** ONE of the following:

**3.1.2.1** Failure to a trial of BOTH of the following as confirmed by claims history or submission of medical records:

- Differin OTC (over the counter)
- Tretinoin cream (generic Retin-A cream)

**OR**

**3.1.2.2** History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- Differin OTC
- Tretinoin cream (generic Retin-A cream)

**OR**

**3.2** BOTH of the following:

**3.2.1** Patient does NOT have a diagnosis of acne vulgaris

**AND**

**3.2.2** ONE of the following:

**3.2.2.1** Failure to a trial of at least THREE preferred\* products as confirmed by claims history or submission of medical records

**OR**

**3.2.2.2** History of intolerance or contraindication to ALL preferred\* products (please specify intolerance or contraindication)

Notes

\*Step therapy is not limited to topical retinoids. In instances where there are fewer than three preferred alternatives, the patient must have a history of failure, contraindication, or intolerance to ALL of the preferred products.  
\*See Table 2 in Background for PDL links.

Product Name:generic tretinoin cream

Approval Length 12 month(s)

Guideline Type Prior Authorization

**Approval Criteria**

**1** - Patient is less than 18 years old

**OR**

**2** - ALL of the following:

**2.1** Patient is 18 years of age or older

**AND**

**2.2** Patient has a non-cosmetic medical condition (e.g., acne vulgaris, psoriasis, precancerous skin lesions) (See Table 1 in Background for additional list of non-cosmetic medical conditions)

**AND**

**2.3** Medication is not being requested solely for cosmetic purposes (e.g., photo-aging, wrinkling, hyperpigmentation, sun damage, melasma) (See Table 1 in Background for additional list of non-cosmetic medical conditions)

## 2 . Background

### Benefit/Coverage/Program Information

**Table 1: Examples of non-cosmetic medical conditions include, but are not limited to, the following:**

|                        |                                   |
|------------------------|-----------------------------------|
| Acanthosis nigricans   | Keratoderma                       |
| Acne                   | Keratoderma palmaris et plantaris |
| Acne keloidalis nuchae | Keratosis rubra figurata          |
| Acne rosacea           | Kyrle's disease                   |
| Acne vulgaris          | Lamellar ichthyosis               |
| Actinic cheilitis      | Leukoplakia                       |
| Actinic dermatitis     | Lichen planus                     |
| Actinic keratosis      | Mal de Meleda                     |
|                        | Malignancy                        |
| Basal cell carcinoma   | Mendes da Costa syndrome          |

|                               |                                       |
|-------------------------------|---------------------------------------|
| Bowen's disease               | Molluscum contagiosum                 |
| Cystic acne                   | Non-bullous congenital ichthyosis     |
| Darier's disease              | Papillon-Lefevre syndrome             |
| Darier-White Disease          | Porokeratosis                         |
| Dermal mucinosis              | Pseudofollicular barbae               |
| Discoid lupus erythematosus   | Pseudoacanthosis nigricans            |
| Epidermoid cysts              | Psoriasis                             |
| Epidermolytic hyperkeratosis  | Psoriasis erythrodermic, palmoplantar |
| Erythrokeratoderma variabilis | Psoriasis pustular                    |
| Favre Racouchot disease       | Psoriatic arthritis                   |
| Flat warts                    | Rosacea                               |
| Folliculitis                  | Sebaceous cysts                       |
| Fox Fordyce disease           | Senile keratosis                      |
| Grover's disease              | Solar keratosis                       |
| Hidradenitis suppurativa      | Squamous cell carcinoma               |
| Hyperkeratosis                | Systematized epidermal nevus          |
| Hyperkeratosis follicularis   | Transient acantholytic dermatosis     |
| Hyperkeratotic eczema         | Tylotic eczema                        |
| Ichthyoses                    | X-linked ichthyosis                   |
| Ichthyosis vulgaris           | Verruca planae                        |
| Keloid scar                   | Von Zumbusch pustular                 |
| Keratoacanthoma               | Warts                                 |
| Keratosis follicularis        | Wound healing (mild)                  |

**Table 2: PDL links**

|            |                                                                                                                                                                                                                                                                               |
|------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| CO:        | <a href="https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html</a>                               |
| HI:        | <a href="https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html</a>                                   |
| MD:        | <a href="https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-cp-pharmacy.html</a>                               |
| NJ:        | <a href="https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html</a>                           |
| NY/NY EPP: | <a href="https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html</a>                               |
| PA CHIP:   | <a href="https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP">https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP</a> |
| RI:        | <a href="https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html</a>                       |

### 3 . Revision History

| Date      | Notes        |
|-----------|--------------|
| 12/3/2024 | Updated GPIs |

Trelegy Ellipta, Breztri



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-398257                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Guideline Name</b> | Trelegy Ellipta, Breztri                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 10/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                                                   |                                              |
|---------------------------------------------------|----------------------------------------------|
| Product Name: Trelegy Ellipta, Breztri Aerosphere |                                              |
| Diagnosis                                         | Chronic Obstructive Pulmonary Disease (COPD) |
| Approval Length                                   | 12 month(s)                                  |
| Guideline Type                                    | Prior Authorization                          |
|                                                   |                                              |



## **Approval Criteria**

**1** - Diagnosis of chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema

**AND**

**2** - ONE of the following:

**2.1** Failure to a 30 day trial of ONE of the following combinations as confirmed by claims history or submission of medical records:

**2.1.1** ONE of the following long-acting muscarinic antagonist (LAMA) plus long-acting beta2-agonist (LABA)

- Anoro Ellipta (umeclidinium/vilanterol)
- Stiolto Respimat (tiotropium/olodaterol)

**OR**

**2.1.2** ONE of the following inhaled corticosteroid (ICS) plus long-acting beta2-agonist (LABA)

- Fluticasone propionate/salmeterol diskus (generic Advair Diskus) or Wixela Inhub (generic Advair Diskus)
- Breyna or budesonide/formoterol (generic of Symbicort)
- Fluticasone/vilanterol (authorized generic of Breo Ellipta)

**OR**

**2.2** History of contraindication or intolerance to ALL of the following (please specify intolerance or contraindication):

- Anoro Ellipta (umeclidinium/vilanterol)
- Stiolto Respimat (tiotropium/olodaterol)
- fluticasone propionate/salmeterol diskus (generic Advair Diskus) or Wixela Inhub (generic Advair Diskus)
- Breyna or budesonide/formoterol (generic of Symbicort)
- Fluticasone/vilanterol (authorized generic of Breo Ellipta)

**OR**

**2.3** Eosinophil count greater than or equal to 300 cells/microliter as confirmed by submission of medical records

|                               |                     |
|-------------------------------|---------------------|
| Product Name: Trelegy Ellipta |                     |
| Diagnosis                     | Asthma              |
| Approval Length               | 12 month(s)         |
| Guideline Type                | Prior Authorization |

**Approval Criteria**

1 - Diagnosis of asthma

**AND**

2 - ONE of the following:

**2.1** Failure to treatment with at least a 30-day trial of ONE of the following, confirmed by claims history or submission of medical records:

- Fluticasone/salmeterol (authorized generic of AirDuo Respiclick)
- Fluticasone propionate/salmeterol diskus (generic Advair Diskus)
- Wixela Inhub (generic Advair Diskus)

**OR**

**2.2** History of contraindication or intolerance to ALL of the following (please specify intolerance or contraindication):

- Fluticasone/salmeterol (authorized generic of AirDuo Respiclick)
- Fluticasone propionate/salmeterol diskus (generic Advair Diskus)
- Wixela Inhub (generic Advair Diskus)

## 2 . Revision History

UnitedHealthcare Community Plan of New Jersey – Clinical Pharmacy Guidelines

| Date      | Notes                                   |
|-----------|-----------------------------------------|
| 9/18/2025 | Updated COPD ICS.LABA step thru agents. |

Tremfya



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-255207                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Guideline Name</b> | Tremfya                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 7/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                      |                       |
|----------------------|-----------------------|
| Product Name:Tremfya |                       |
| Diagnosis            | Plaque Psoriasis      |
| Approval Length      | 12 month(s)           |
| Therapy Stage        | Initial Authorization |
| Guideline Type       | Prior Authorization   |

## **Approval Criteria**

**1** - Diagnosis of chronic moderate to severe plaque psoriasis

**AND**

**2** - Patient is NOT receiving Tremfya in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

**AND**

**3** - Prescribed by or in consultation with a dermatologist

**AND**

**4** - One of the following:

**4.1** Patient is currently on Tremfya therapy as confirmed by claims history or submission of medical records

**OR**

**4.2** All of the following:

**4.2.1** One of the following:

**4.2.1.1** Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of plaque psoriasis as confirmed by claims history or submission of medical records [e.g., Cimzia (certolizumab), adalimumab, Otezla (apremilast), Skyrizi (risankizumab-rzaa), ustekinumab]

**OR**

**4.2.1.2** All of the following:

**4.2.1.2.1** Greater than or equal to 3% body surface area involvement, palmoplantar, facial, or genital involvement, or severe scalp psoriasis

**AND**

**4.2.1.2.2** One of the following:

- Failure to ONE of the following topical therapy classes confirmed by claims history or submission of medical records: Corticosteroids (e.g., betamethasone, clobetasol, desonide), Vitamin D analogs (e.g., calcitriol, calcipotriene), Tazarotene, Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus), Anthralin, Coal tar
- History of intolerance or contraindication to ALL of the following topical therapy classes (please specify intolerance or contraindication): Corticosteroids (e.g., betamethasone, clobetasol, desonide), Vitamin D analogs (e.g., calcitriol, calcipotriene), Tazarotene, Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus), Anthralin, Coal tar

**AND**

**4.2.1.2.3** One of the following:

- Failure to a 3 month trial of methotrexate at maximally indicated dose confirmed by claims history or submitted medical records
- History of intolerance or contraindication to methotrexate (please specify intolerance or contraindication)

**AND**

**4.2.2** One of the following:

**4.2.2.1** Failure to TWO of the following preferred products as confirmed by claims history or submitted medical records:

- One of the preferred adalimumab products\*
- Enbrel (etanercept)
- One of the preferred ustekinumab products\*

**OR**

**4.2.2.2** History of intolerance or contraindication to ALL of the following preferred products (please specify intolerance or contraindication):

- One of the preferred adalimumab products\*
- Enbrel (etanercept)
- One of the preferred ustekinumab products\*

**AND**

**4.2.3** One of the following:

- Failure to Cosentyx (secukinumab) as confirmed by claims history or submission of medical records
- History of intolerance or contraindication to Cosentyx (secukinumab) (please specify intolerance or contraindication)

|       |                              |
|-------|------------------------------|
| Notes | *See PDL links in Background |
|-------|------------------------------|

Product Name:Tremfya

|                 |                           |
|-----------------|---------------------------|
| Diagnosis       | Psoriatic Arthritis (PsA) |
| Approval Length | 12 month(s)               |
| Therapy Stage   | Initial Authorization     |
| Guideline Type  | Prior Authorization       |

### Approval Criteria

**1** - Diagnosis of active psoriatic arthritis

**AND**

**2** - Patient is NOT receiving Tremfya in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Cosentyx (secukinumab), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

**AND**

**3** - Prescribed by or in consultation with one of the following:

- Rheumatologist
- Dermatologist

**AND**

**4** - One of the following:

**4.1** Patient is currently on Tremfya therapy as confirmed by claims history or submission of medical records

**OR**

**4.2** ALL of the following:

**4.2.1** One of the following:

- Failure to a 3 month trial of methotrexate at the maximally indicated dose, confirmed by claims history or submitted medical records
- History of intolerance or contraindication to methotrexate (please specify intolerance or contraindication)
- Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of psoriatic arthritis as confirmed by claims history or submission of medical records [e.g., Cimzia (certolizumab), adalimumab, Simponi (golimumab), ustekinumab, Xeljanz/XR (tofacitinib), Otezla (apremilast), Rinvoq (upadacitinib)]

**AND**

**4.2.2** One of the following:

**4.2.2.1** Failure to TWO of the following preferred products as confirmed by claims history or submitted medical records:

- One of the preferred adalimumab products\*
- Enbrel (etanercept)
- One of the preferred ustekinumab products\*



**OR**

**4.2.2.2** History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication)

- One of the preferred adalimumab products\*
- Enbrel (etanercept)
- One of the preferred ustekinumab products\*

**AND**

**4.2.3** One of the following:

- Failure to Cosentyx (secukinumab) as confirmed by claims history or submitted medical records
- History of intolerance or contraindication to Cosentyx (secukinumab) (please specify intolerance or contraindication)

Notes

\*See PDL links in Background

Product Name: Tremfya

Diagnosis      Ulcerative Colitis (UC)

Approval Length      12 month(s)

Therapy Stage      Initial Authorization

Guideline Type      Prior Authorization

**Approval Criteria**

**1** - Diagnosis of moderately to severely active ulcerative colitis

**AND**

**2** - One of the following:

**2.1** Patient has been established on therapy with Tremfya under an active UnitedHealthcare

medical benefit prior authorization for the treatment of moderately to severely active ulcerative colitis

**OR**

**2.2** Patient is currently on Tremfya therapy for moderately to severely active ulcerative colitis as confirmed by claims history or submission of medical records

**AND**

**3** - Patient is NOT receiving Tremfya in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), ustekinumab, adalimumab, Skyrizi (risankizumab)]

**AND**

**4** - Prescribed by or in consultation with a gastroenterologist

| Product Name:Tremfya                                                                                                                                                                                                                                                           |                       |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Diagnosis                                                                                                                                                                                                                                                                      | Crohn's Disease (CD)  |
| Approval Length                                                                                                                                                                                                                                                                | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                  | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                 | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of moderately to severely active Crohn's disease</p> <p><b>AND</b></p> <p><b>2</b> - ONE of the following:</p> <p><b>2.1</b> Patient has been established on therapy with Tremfya under an active UnitedHealthcare</p> |                       |

medical benefit prior authorization for the treatment of moderately to severely active Crohn's disease

**OR**

**2.2 ONE of the following:**

**2.2.1** Failure to ONE of the following conventional drugs or classes at maximally indicated doses, as confirmed by claims history or submitted medical records:

- Corticosteroids (e.g., prednisone, methylprednisolone, budesonide)
- Azathioprine (generic Imuran)
- 6-mercaptopurine (generic Purinethol)
- Methotrexate

**OR**

**2.2.2** History of intolerance or contraindication to ALL of the following conventional drugs or classes (please specify intolerance or contraindication):

- Corticosteroids (e.g., prednisone, methylprednisolone, budesonide)
- Azathioprine (generic Imuran)
- 6-mercaptopurine (generic Purinethol)
- Methotrexate

**OR**

**2.2.3** Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of Crohn's disease as confirmed by claims history or submission of medical records [e.g., adalimumab, Cimzia (certolizumab), Entyvio (vedolizumab), Omvoh (mirikizumab-mrkz), Rinvoq (upadaci-tinib), Skyrizi (risankizumab), ustekinumab]

**OR**

**2.3** Patient is currently on Tremfya therapy for moderately to severely active Crohn's disease as confirmed by claims history or submission of medical records

**AND**

**3** - Patient is NOT receiving Tremfya in combination with another targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Entyvio (vedolizumab), Omvoh (miri-kizumab-mrkz), Rinvoq (upadacitinib), Skyrizi (risankizumab), ustekinumab]

**AND**

**4** - Prescribed by or in consultation with a gastroenterologist

**Product Name:**Tremfya

|           |                                                                                            |
|-----------|--------------------------------------------------------------------------------------------|
| Diagnosis | Plaque Psoriasis, Psoriatic Arthritis (PsA), Ulcerative Colitis (UC), Crohn's Disease (CD) |
|-----------|--------------------------------------------------------------------------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                 |
|---------------|-----------------|
| Therapy Stage | Reauthorization |
|---------------|-----------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

### Approval Criteria

**1** - Documentation of positive clinical response to Tremfya therapy

**AND**

**2** - Patient is NOT receiving Tremfya in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Entyvio (vedolizumab), Omvoh (mirikizumab-mrkz), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]\*

|       |                                                                               |
|-------|-------------------------------------------------------------------------------|
| Notes | *Examples of drug(s) may not be applicable based on the requested indication. |
|-------|-------------------------------------------------------------------------------|

## 2 . Background

**Benefit/Coverage/Program Information**

## PDL Links

CO: <https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html>

HI: <https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html>

MD: <https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-cp-pharmacy.html>

NJ: <https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html>

NY: <https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html>

PA: <https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP>

RI: <https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html>

NM: <https://www.uhcprovider.com/en/health-plans-by-state/new-mexico-health-plans/nm-comm-plan-home/nm-cp-pharmacy.html>

## 3 . Revision History

| Date     | Notes                                            |
|----------|--------------------------------------------------|
| 5/8/2025 | Updated GPIs. Added criteria for Crohn's Disease |

Trikafta



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-230189                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Guideline Name</b> | Trikafta                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 5/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                        |                       |
|------------------------|-----------------------|
| Product Name: Trikafta |                       |
| Diagnosis              | Cystic Fibrosis       |
| Approval Length        | 12 month(s)           |
| Therapy Stage          | Initial Authorization |
| Guideline Type         | Prior Authorization   |

**Approval Criteria**

1 - Diagnosis of cystic fibrosis (CF)

**AND**

2 - Submission of laboratory results documenting that the patient has at least ONE of the following responsive mutations in the CFTR gene (see Table 1 in Background):

- F508del mutation
- A mutation that is responsive based on clinical data
- A mutation that is responsive based on in vitro data
- A mutation that is responsive based on extrapolated data

**AND**

3 - Patient is 2 years of age or older

**AND**

4 - Prescribed by, or in consultation with a provider who specializes in the treatment of CF

|                                                                                                                                                                 |                     |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name: Trikafta                                                                                                                                          |                     |
| Diagnosis                                                                                                                                                       | Cystic Fibrosis     |
| Approval Length                                                                                                                                                 | 12 month(s)         |
| Therapy Stage                                                                                                                                                   | Reauthorization     |
| Guideline Type                                                                                                                                                  | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p>1 - Documentation of positive clinical response to Trikafta therapy (e.g., improved lung function, stable lung function)</p> |                     |

## 2 . Background

### Benefit/Coverage/Program Information

**Table 1: List of CFTR Gene Mutations Responsive to Trikafta**

| List of CFTR Gene Mutations Responsive to Trikafta |                  |         |                        |        |
|----------------------------------------------------|------------------|---------|------------------------|--------|
| Based on clinical data**                           |                  |         |                        |        |
| 2789+5G→A                                          | D1152H†          | L206W†  | R1066H†                | S945L† |
| 3272-26A→G                                         | F508del†         | L997F†  | R117C†                 | T338I† |
| 3849+10kbC→T                                       | G85E†            | M1101K† | R347H†                 | V232D† |
| A455E†                                             | L1077P†          | P5L†    | R347P†                 |        |
| Based on <i>in vitro</i> data‡                     |                  |         |                        |        |
| N1303K                                             | F200I            | I1139V  | P574H                  | S1045Y |
| 1507_1515del9                                      | F311del          | I125T   | P67L                   | S108F  |
| 2183A→G                                            | F311L            | I1269N  | P750L                  | S1118F |
| 3141del9                                           | F508C            | I1366N  | Q1291R                 | S1159F |
| 546insCTA                                          | F508C;<br>S1251N | I148N   | Q1313K                 | S1159P |
| A1006E                                             | F575Y            | I148T   | Q237E                  | S1235R |
| A1067P                                             | F587I            | I175V   | Q237H                  | S1251N |
| A1067T                                             | G1047R           | I331N   | Q359R                  | S1255P |
| A107G                                              | G1061R           | I336K   | Q372H                  | S13F   |
| A120T                                              | G1069R           | I502T   | Q493R                  | S341P  |
| A234D                                              | G1123R           | I506L   | Q552P                  | S364P  |
| A309D                                              | G1244E           | I556V   | Q98R                   | S492F  |
| A349V                                              | G1247R           | I601F   | R1048G                 | S549I  |
| A46D                                               | G1249R           | I618T   | R1070Q                 | S549N  |
| A554E                                              | G126D            | I807M   | R1070W                 | S549R  |
| A62P                                               | G1349D           | I980K   | R1162L                 | S589N  |
| C491R                                              | G178E            | K1060T  | R117C; G576A;<br>R668C | S737F  |
| D110E                                              | G178R            | K162E   | R117G                  | S912L  |
| D110H                                              | G194R            | K464E   | R117H                  | S977F  |
| D1270N                                             | G194V            | L1011S  | R117L                  | T1036N |
| D1445N                                             | G27E             | L1324P  | R117P                  | T1053I |
| D192G                                              | G27R             | L1335P  | R1283M                 | T1086I |
| D443Y                                              | G314E            | L137P   | R1283S                 | T1246I |



|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |              |            |                        |        |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|------------|------------------------|--------|
| D443Y; G576A;<br>R668C                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | G424S        | L1480P     | R170H                  | T1299I |
| D565G                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | G463V        | L15P       | R258G                  | T351I  |
| D579G                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | G480C        | L165S      | R297Q                  | V1153E |
| D614G                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | G480S        | L320V      | R31C                   | V1240G |
| D836Y                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | G551A        | L333F      | R31L                   | V1293G |
| D924N                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | G551D        | L333H      | R334L                  | V201M  |
| D979V                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | G551S        | L346P      | R334Q                  | V392G  |
| D993Y                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | G576A        | L441P      | R347L                  | V456A  |
| E116K                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | G576A; R668C | L453S      | R352Q                  | V456F  |
| E116Q                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | G622D        | L619S      | R352W                  | V562I  |
| E193K                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | G628R        | L967S      | R516S                  | V603F  |
| E292K                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | G970D        | M1137V     | R553Q                  | V754M  |
| E474K                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | H1054D       | M152V      | R668C                  | W1282R |
| E56K                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | H1085P       | M265R      | R709Q                  | W361R  |
| E588V                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | H1085R       | M952I      | R74Q                   | Y1014C |
| E60K                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | H1375P       | M952T      | R74W                   | Y1032C |
| E92K                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | H199Y        | N1303I     | R74W; V201M            | Y161D  |
| F1016S                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | H620P        | N186K      | R74W; V201M;<br>D1270N | Y161S  |
| F1052V                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | H620Q        | N187K      | R751L                  | Y301C  |
| F1074L                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | H939R        | N418S      | R75L                   | Y563N  |
| F1099L                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | H939R; H949L | P140S      | R75Q                   |        |
| F1107L                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | I1027T       | P205S      | R792G                  |        |
| F191V                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | I105N        | P499A      | R933G                  |        |
| Based on extrapolation from Trial 5§                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |              |            |                        |        |
| 4005+2T→C                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 2789+2insA   | 3849+40A→G | 5T; TG13               |        |
| 1341G→A                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 296+28A→G    | 3849+4A→G  | 621+3A→G               |        |
| 1898+3A→G                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 3041-15T→G   | 3850-3T→G  | 711+3A→G               |        |
| 2752-26A→G                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 3600G→A      | 5T; TG12   | E831X                  |        |
| <p>** Clinical data obtained from Trials 1 (NCT03525444), 2 (NCT03525548), and 5 (NCT05274269).</p> <p>† This mutation is also predicted to be responsive by FRT assay.</p> <p>‡ The N1303K mutation is predicted to be responsive by HBE assay. All other mutations predicted to be responsive with in vitro data are supported by FRT assay.</p> <p>§ Efficacy is extrapolated from Trial 5 to non-canonical splice mutations because clinical trials in all mutations of this subgroup are infeasible and these mutations are not amenable to interrogation by FRT system.</p> |              |            |                        |        |

### 3 . Revision History

| Date      | Notes                                                           |
|-----------|-----------------------------------------------------------------|
| 3/26/2025 | Updated criteria and table in background. Combined formularies. |

## Tryptans



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-208201                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Guideline Name</b> | Tryptans                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 4/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                         |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|
| Product Name: almotriptan, generic eletriptan, Brand Relpax, generic frovatriptan, Brand Frova, Onzetra XSail, generic rizatriptan, Brand Maxalt, generic rizatriptan ODT, Brand Maxalt-MLT, Imitrex Statdose System, sumatriptan auto-inj, Brand Imitrex nasal spr/tabs, generic sumatriptan nasal spr/tabs/inj, Brand Imitrex Statdose Refill, generic sumatriptan refill, generic sumatriptan/naproxen, Brand Treximet, Zembrace Symtouch, generic zolmitriptan tabs/nasal spr, Brand Zomig tabs/nasal spr, Brand Zolmitriptan nasal spr, zolmitriptan ODT, Tosymra |                         |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Non-Preferred Products* |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 12 month(s)             |

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Prior Authorization       |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| <p><b>Approval Criteria</b></p> <p><b>1</b> - If the requested medication is non-preferred*, BOTH of the following:</p> <p><b>1.1</b> Diagnosis of migraine headaches with or without aura</p> <p style="text-align: center;"><b>AND</b></p> <p><b>1.2</b> ONE of the following:</p> <p><b>1.2.1</b> Patient has failure to THREE of the following as confirmed by claims history or submission of medical records:</p> <ul style="list-style-type: none"> <li>• Eletriptan (generic Relpax)</li> <li>• Naratriptan</li> <li>• Rizatriptan</li> <li>• One of the following sumatriptan formulations: tablets, nasal spray, 4 mg injection, or 6 mg injection</li> <li>• Zolmitriptan (generic Zomig)</li> </ul> <p style="text-align: center;"><b>OR</b></p> <p><b>1.2.2</b> Patient has a history of contraindication or intolerance to ALL of the following (please specify intolerance or contraindication):</p> <ul style="list-style-type: none"> <li>• Eletriptan (generic Relpax)</li> <li>• Naratriptan</li> <li>• Rizatriptan</li> <li>• One of the following sumatriptan formulations: tablets, nasal spray, 4 mg injection, or 6 mg injection</li> <li>• Zolmitriptan (generic Zomig)</li> </ul> |                           |
| Notes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | *PDL links in Background. |

Product Name: Imitrex Statdose System, sumatriptan auto-inj, sumatriptan inj, Brand Imitrex Statdose Refill, generic sumatriptan refill

Diagnosis      Migraine Headaches

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 12 month(s)    |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Quantity Limit |
| <p><b>Approval Criteria</b></p> <p><b>1 - Diagnosis of migraine headaches with or without aura</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>2 - Currently receiving prophylactic therapy with at least ONE of the following as confirmed by claims history or submission of medical records:</b></p> <ul style="list-style-type: none"> <li>• A beta-blocker (i.e., atenolol, metoprolol, nadolol, propranolol, or timolol*)</li> <li>• Candesartan* (generic Atacand)</li> <li>• A calcitonin gene-related peptide receptor (CGRP) antagonist or inhibitor for preventive treatment of migraine*** [i.e., Aimovig, Ajovy*, Emgality, Qulipta*, Vyepti**]</li> <li>• Divalproex sodium (generic Depakote/Depakote ER)</li> <li>• OnabotulinumtoxinA (generic Botox)**</li> <li>• A serotonin-norepinephrine reuptake inhibitor [i.e., duloxetine (Cymbalta), venlafaxine (Effexor/Effexor XR)]</li> <li>• Topiramate (generic Topamax)</li> <li>• A tricyclic antidepressant [i.e., amitriptyline (Elavil), nortriptyline (Pamelor)]</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>3 - ONE of the following:</b></p> <p><b>3.1 Higher dose or quantity is supported in the dosage and administration section of the manufacturer's prescribing information</b></p> <p style="text-align: center;"><b>OR</b></p> <p><b>3.2 Higher dose or quantity is supported by one of the following compendia:</b></p> <ul style="list-style-type: none"> <li>• American Hospital Formulary Service Drug Information</li> <li>• Thomson Micromedex DrugDex</li> <li>• Clinical pharmacology</li> <li>• United States Pharmacopoeia-National Formulary (USP-NF)</li> </ul> |                |

**OR**

**3.3** Provider provides evidence from published biomedical literature to support safety and additional efficacy at doses/quantities greater than those approved by the FDA for the diagnosis indicated

**AND**

**4** - Provider acknowledges that the potential benefit outweighs the risk associated with the higher dose or quantity

|       |                                                                                                                                                                                                                                               |
|-------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Notes | <p>See Table 1 in Background.</p> <p>*This is non-preferred and should not be included in denial to provider.</p> <p>**This is a medical benefit and should not be included in denial to provider.</p> <p>***Requires prior authorization</p> |
|-------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

Product Name: Imitrex Statdose System, sumatriptan auto-inj, sumatriptan inj, Brand Imitrex Statdose Refill, generic sumatriptan refill

|                 |                   |
|-----------------|-------------------|
| Diagnosis       | Cluster Headaches |
| Approval Length | 12 month(s)       |
| Guideline Type  | Quantity Limit    |

### Approval Criteria

**1** - Diagnosis of cluster headaches

**AND**

**2** - Patient has experienced at least 2 cluster periods lasting from 7 days to 365 days, separated by pain-free periods lasting at least three months

**AND**

**3** - ONE of the following:

**3.1** Higher dose or quantity is supported in the dosage and administration section of the manufacturer's prescribing information

**OR**

**3.2** Higher dose or quantity is supported by one of the following compendia:

- American Hospital Formulary Service Drug Information
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopoeia-National Formulary (USP-NF)

**OR**

**3.3** Provider provides evidence from published biomedical literature to support safety and additional efficacy at doses/quantities greater than those approved by the FDA for the diagnosis indicated

**AND**

**4** - Provider acknowledges that the potential benefit outweighs the risk associated with the higher dose or quantity

|       |                            |
|-------|----------------------------|
| Notes | See Table 1 in Background. |
|-------|----------------------------|

Product Name: almotriptan, generic eletriptan, Brand Relpax, generic frovatriptan, Brand Frova, Onzetra XSail, generic rizatriptan, Brand Maxalt, generic rizatriptan ODT, Brand Maxalt-MLT, Brand Imitrex nasal spr/tabs, generic sumatriptan nasal spr/tabs, generic sumatriptan/naproxen, Brand Treximet, Zembrace Syntouch, generic zolmitriptan tabs/nasal spr, Brand Zomig tabs/nasal spr, Brand Zolmitriptan nasal spr, zolmitriptan ODT, Tosymra, generic naratriptan

|                 |                |
|-----------------|----------------|
| Approval Length | 12 month(s)    |
| Guideline Type  | Quantity Limit |

#### Approval Criteria

**1** - Diagnosis of migraine headaches with or without aura

**AND**

**2** - Currently receiving prophylactic therapy with at least ONE of the following as confirmed by claims history or submission of medical records:

- A beta-blocker (i.e., atenolol, metoprolol, nadolol, propranolol, or timolol\*)
- Candesartan\* (generic Atacand)
- A calcitonin gene-related peptide receptor (CGRP) antagonist or inhibitor for preventive treatment of migraine\*\*\* [i.e., Aimovig, Ajovy\*, Emgality, Qulipta\*, Vyepti\*\*]
- Divalproex sodium (generic Depakote/Depakote ER)
- OnabotulinumtoxinA (generic Botox)\*\*
- A serotonin-norepinephrine reuptake inhibitor [i.e., duloxetine (Cymbalta), venlafaxine (Effexor/Effexor XR)]
- Topiramate (generic Topamax)
- A tricyclic antidepressant [i.e., amitriptyline (Elavil), nortriptyline (Pamelor)]

**AND**

**3** - ONE of the following:

**3.1** Higher dose or quantity is supported in the dosage and administration section of the manufacturer's prescribing information

**OR**

**3.2** Higher dose or quantity is supported by one of the following compendia:

- American Hospital Formulary Service Drug Information
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopoeia-National Formulary (USP-NF)

**OR**

**3.3** Provider provides evidence from published biomedical literature to support safety and additional efficacy at doses/quantities greater than those approved by the FDA for the diagnosis indicated



**AND**

**4** - Provider acknowledges that the potential benefit outweighs the risk associated with the higher dose or quantity

|       |                                                                                                                                                                                                                                              |
|-------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Notes | <p>See Table 1 in Background.</p> <p>*This is non-preferred and should not be included in denial to provider</p> <p>**This is a medical benefit and should not be included in denial to provider.</p> <p>***Requires prior authorization</p> |
|-------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

## 2 . Background

### Benefit/Coverage/Program Information

**Table 1. Quantity Limits**

| Drug Name                                            | Strength             | Quantity Limit |
|------------------------------------------------------|----------------------|----------------|
| Brand Amerge<br>generic naratriptan                  | 1mg, 2.5mg           | 9 tabs/month   |
| Brand Frova<br>Generic frovatriptan                  | 2.5mg                | 9 tabs/month   |
| Brand Imitrex tablets<br>Generic sumatriptan tablets | 25mg, 50mg,<br>100mg | 9 tabs/month   |
| Brand Maxalt<br>Generic rizatriptan                  | 5mg, 10mg            | 9 tabs/month   |

|                                                                                             |                                      |                                                                                       |
|---------------------------------------------------------------------------------------------|--------------------------------------|---------------------------------------------------------------------------------------|
| Brand Maxalt MLT<br>Generic rizatriptan ODT                                                 | 5mg, 10mg                            | 9 tabs/month                                                                          |
| Generic almotriptan                                                                         | 6.25mg, 12.5mg                       | 6 tabs/month                                                                          |
| Relpax<br>Generic eletriptan                                                                | 20mg, 40mg                           | 6 tabs/month                                                                          |
| Brand Zomig<br>Generic zolmitriptan                                                         | 2.5mg, 5mg                           | 6 tabs/month                                                                          |
| Brand Zomig ZMT<br>Generic zolmitriptan ODT                                                 | 2.5mg, 5mg                           | 6 tabs/month                                                                          |
| Brand Imitrex nasal spray<br>Generic sumatriptan nasal spray                                | 5mg, 20mg                            | 6 spray<br>devices/month                                                              |
| Zomig nasal spray                                                                           | 2.5mg, 5mg                           | 6 spray<br>devices/month                                                              |
| Treximet<br>Generic sumatriptan/naproxen                                                    | 85mg/500 mg,<br>10mg/60mg            | 9 tabs/month                                                                          |
| Onzetra Xsail                                                                               | 11mg                                 | 1 box (8 units)/month                                                                 |
| Zembrace SymTouch                                                                           | 3mg/ <u>0.5mL</u>                    | <u>2 boxes</u> ( <u>8</u><br>units)/month                                             |
| <u>Brand Imitrex</u><br><u>Generic Sumatriptan</u><br><u>Autoinjector/Cartridge Refills</u> | <u>4mg/0.5mL</u><br><u>6mg/0.5mL</u> | <u>8 autoinjectors or</u><br><u>cartridge refills/month</u><br><u>(4 boxes/month)</u> |
| <u>Brand Imitrex</u><br><u>Generic Sumatriptan</u><br><u>Vials</u>                          | <u>6mg/0.5mL</u>                     | <u>10 vials/month (2</u><br><u>boxes/month)</u>                                       |

|                                                         |                  |                                                       |
|---------------------------------------------------------|------------------|-------------------------------------------------------|
| <u>Generic Sumatriptan</u><br><u>Pre-filled Syringe</u> | <u>6mg/0.5mL</u> | <u>8 prefilled syringes (4</u><br><u>boxes/month)</u> |
| <u>Tosymra nasal spray</u>                              | <u>10mg</u>      | <u>6 units per month</u>                              |

**PDL links**

CO: <https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html>

HI: <https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html>

NJ: <https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html>

NM: <https://www.uhcprovider.com/en/health-plans-by-state/new-mexico-health-plans/nm-comm-plan-home/nm-cp-pharmacy.html>

NY: <https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html>

PA: <https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP>

RI: <https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html>

### 3 . Revision History

| Date     | Notes                                                                                                                                                                                    |
|----------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 3/5/2025 | Updated formularies. Removed naratriptan step therapy section. Add ed eletriptan and zolmitriptan as options in the non-preferred section. Updated prophylactic therapies list and notes |



Truqap



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-202194                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Guideline Name</b> | Truqap                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 4/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                     |                       |
|---------------------|-----------------------|
| Product Name:Truqap |                       |
| Diagnosis           | Breast Cancer         |
| Approval Length     | 12 month(s)           |
| Therapy Stage       | Initial Authorization |

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Prior Authorization |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of breast cancer</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Disease is ONE of the following:</p> <ul style="list-style-type: none"> <li>• Locally advanced</li> <li>• Recurrent unresectable (local or regional)</li> <li>• Metastatic</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Disease is hormone receptor (HR)-positive</p> <p style="text-align: center;"><b>AND</b></p> <p><b>4</b> - Disease is human epidermal growth factor receptor 2 (HER2)-negative</p> <p style="text-align: center;"><b>AND</b></p> <p><b>5</b> - Presence of one or more PIK3CA/AKT1/PTEN-alterations</p> <p style="text-align: center;"><b>AND</b></p> <p><b>6</b> - ONE of the following:</p> <p><b>6.1</b> Has progressed on at least one endocrine-based regimen in the metastatic setting (e.g., anastrozole, letrozole, exemestane, tamoxifen)</p> <p style="text-align: center;"><b>OR</b></p> |                     |

**6.2** Recurrence on or within 12 months of completing adjuvant therapy

**AND**

**7** - Used in combination with fulvestrant

|                                                                                                                                                                                                          |                     |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Truqap                                                                                                                                                                                      |                     |
| Diagnosis                                                                                                                                                                                                | Breast Cancer       |
| Approval Length                                                                                                                                                                                          | 12 month(s)         |
| Therapy Stage                                                                                                                                                                                            | Reauthorization     |
| Guideline Type                                                                                                                                                                                           | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Patient does not show evidence of progressive disease while on Truqap therapy</p> <p><b>AND</b></p> <p><b>2</b> - Used in combination with fulvestrant</p> |                     |

|                                                                                                                                                       |                           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Truqap                                                                                                                                   |                           |
| Diagnosis                                                                                                                                             | NCCN Recommended Regimens |
| Approval Length                                                                                                                                       | 12 month(s)               |
| Therapy Stage                                                                                                                                         | Initial Authorization     |
| Guideline Type                                                                                                                                        | Prior Authorization       |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium</p> |                           |

|                                                                                                          |                           |
|----------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Truqap                                                                                      |                           |
| Diagnosis                                                                                                | NCCN Recommended Regimens |
| Approval Length                                                                                          | 12 month(s)               |
| Therapy Stage                                                                                            | Reauthorization           |
| Guideline Type                                                                                           | Prior Authorization       |
| <p><b>Approval Criteria</b></p> <p>1 - Documentation of positive clinical response to Truqap therapy</p> |                           |

## 2 . Revision History

| Date      | Notes                                                                                                                                                                          |
|-----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 2/25/2025 | Combined formularies. Added new GPIs for Truqap therapy packs. F or BC initial auth section, added "recurrent unresectable (local or regional)" as an option for disease type. |



Tryngolza



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-422542                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Guideline Name</b> | Tryngolza                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Michigan (ACUMI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 11/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                        |                       |
|------------------------|-----------------------|
| Product Name:Tryngolza |                       |
| Approval Length        | 12 month(s)           |
| Therapy Stage          | Initial Authorization |
| Guideline Type         | Prior Authorization   |

### Approval Criteria

**1** - Diagnosis of familial chylomicronemia syndrome (FCS) (i.e., monogenic chylomicronemia, type 1 hyperlipoproteinemia)

**AND**

**2** - Diagnosis has been confirmed by BOTH of the following:

**2.1** One of the following:

**2.1.1** Genetic confirmation of biallelic pathogenic variants (i.e., homozygosity, compound heterozygosity or double heterozygosity) in FCS-causing genes (i.e., LPL, GPIHBP1, APOA5, APOC2, or LMF1)

**OR**

**2.1.2** North American FCS (NAFCS) score greater than or equal to 45

**AND**

**2.2** Untreated fasting triglyceride levels greater than or equal to 880 mg/dL

**AND**

**3** - Prescribed by one of the following:

- Cardiologist
- Endocrinologist
- Gastroenterologist
- Lipid specialist (lipidologist)

Product Name: Tryngolza

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                     |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of positive clinical response to Tryngolza therapy (e.g., reduction in triglycerides, reduction in episodes of acute pancreatitis)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Prescribed by one of the following:</p> <ul style="list-style-type: none"> <li>• Cardiologist</li> <li>• Endocrinologist</li> <li>• Gastroenterologist</li> <li>• Lipid specialist (lipidologist)</li> </ul> |                     |

## 2 . Revision History

| Date       | Notes      |
|------------|------------|
| 10/22/2025 | Removed IN |

Tryvio



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|-----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-242205                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Guideline Name</b> | Tryvio                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Washington (ACUWA, ACUWAAHE, ACUWAC)</li> <li>• Medicaid - Community &amp; State Pennsylvania (ACUPA)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 6/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                      |
|----------------------|
| Product Name: Tryvio |
|----------------------|

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                       |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1 - Diagnosis of resistant hypertension</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>2 - ONE of the following:</b></p> <ul style="list-style-type: none"> <li>Systolic blood pressure greater than or equal to 130 mm Hg (millimeters of mercury) on two consecutive measurements despite maximally tolerated antihypertensive treatment</li> <li>Diastolic blood pressure greater than or equal to 80 mm Hg on two consecutive measurements despite maximally tolerated antihypertensive treatment</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>3 - Patient has been previously treated with ALL of the following antihypertensive classes for an adequate duration (minimum 4 weeks each) at a maximally tolerated dose as confirmed by claims history or submission of medical records:</b></p> <ul style="list-style-type: none"> <li>Maximally tolerated blocker of the renin-angiotensin system [angiotensin-converting enzyme (ACE) inhibitor (e.g., enalapril, lisinopril) or angiotensin II receptor blocker (ARB) (e.g., candesartan, valsartan)]</li> <li>Maximally tolerated calcium channel blocker (e.g., amlodipine, diltiazem, verapamil)</li> <li>Maximally tolerated diuretics (e.g., hydrochlorothiazide)</li> <li>Maximally tolerated mineralocorticoid receptor antagonist [MRA (e.g., spironolactone, eplerenone)]</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>4 - Provider attests other causes of hypertension have been excluded (e.g., secondary causes [e.g., primary hyperaldosteronism], white coat effect, medication nonadherence)</b></p> |                       |

**AND**

**5** - Used as an adjunct to lifestyle modification (e.g., dietary or caloric restriction, exercise, behavioral support, community-based program)

**AND**

**6** - Tryvio will be used in combination with at least 3 antihypertensive medications from different classes at maximally tolerated doses

**AND**

**7** - Prescribed by or in consultation with a specialist experienced in the treatment of resistant hypertension (e.g., cardiologist, nephrologist)

|                                                                                                                                                                                                                                                                                                     |                     |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Tryvio                                                                                                                                                                                                                                                                                 |                     |
| Approval Length                                                                                                                                                                                                                                                                                     | 12 month(s)         |
| Therapy Stage                                                                                                                                                                                                                                                                                       | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                                                                      | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation the patient is receiving clinical benefit to Tryvio therapy</p> <p><b>AND</b></p> <p><b>2</b> - Tryvio will be used in combination with at least 3 antihypertensive medications from different classes at maximally tolerated doses</p> |                     |

Tukysa



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-333229                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Guideline Name</b> | Tukysa                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 8/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                     |                       |
|---------------------|-----------------------|
| Product Name:Tukysa |                       |
| Diagnosis           | Breast Cancer         |
| Approval Length     | 12 month(s)           |
| Therapy Stage       | Initial Authorization |

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Prior Authorization |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of breast cancer</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Disease is ONE of the following:</p> <ul style="list-style-type: none"> <li>Advanced unresectable</li> <li>Metastatic</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Disease is human epidermal growth factor receptor 2 (HER2)-positive</p> <p style="text-align: center;"><b>AND</b></p> <p><b>4</b> - Patient has been previously treated with an anti-HER2-based regimen in the metastatic setting (e.g., trastuzumab [Kanjinti, Ogivri, Trazimera], pertuzumab [Perjeta], ado-trastuzumab emtansine [Kadcyla])</p> <p style="text-align: center;"><b>AND</b></p> <p><b>5</b> - Used in combination with trastuzumab (e.g., Kanjinti, Ogivri, Trazimera) and capecitabine (Xeloda)</p> |                     |

|                      |                       |
|----------------------|-----------------------|
| Product Name: Tukysa |                       |
| Diagnosis            | CNS Cancers           |
| Approval Length      | 12 month(s)           |
| Therapy Stage        | Initial Authorization |
| Guideline Type       | Prior Authorization   |



**Approval Criteria**

**1** - Diagnosis of brain metastases with HER2 (human epidermal growth factor receptor 2) positive breast cancer

**AND**

**2** - Patient has been previously treated with an anti-HER2-based regimen (e.g., trastuzumab [Kanjinti, Ogivri, Trazimera], pertuzumab [Perjeta], ado-trastuzumab emtansine [Kadcyla])

**AND**

**3** - Used in combination with trastuzumab (e.g., Kanjinti, Ogivri, Trazimera) and capecitabine (Xeloda)

|                                                                                                                                                                                                                                                                                                            |                       |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Tukysa                                                                                                                                                                                                                                                                                        |                       |
| Diagnosis                                                                                                                                                                                                                                                                                                  | Colorectal Cancer     |
| Approval Length                                                                                                                                                                                                                                                                                            | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                              | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                             | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of unresectable, advanced, or metastatic colorectal cancer [HER2-amplified and RAS (gene) and BRAF (gene) wild-type]</p> <p><b>AND</b></p> <p><b>2</b> - Disease is human epidermal growth factor receptor 2 (HER2)-positive</p> <p><b>AND</b></p> |                       |

**3 - ONE of the following:**

**3.1** Patient has previously been treated with ONE of the following regimens:

- Fluoropyrimidine-based chemotherapy
- Oxaliplatin-based chemotherapy
- Irinotecan-based chemotherapy

**OR**

**3.2** Patient is not appropriate for intensive therapy

**AND**

**4 -** Used in combination with trastuzumab (e.g., Kanjinti, Ogivri, Trazimera)

|                                                                                                                                                                                                                                                                                                                                                           |                       |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Tukysa                                                                                                                                                                                                                                                                                                                                       |                       |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                 | Biliary Tract Cancers |
| Approval Length                                                                                                                                                                                                                                                                                                                                           | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                             | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                            | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1 -</b> Diagnosis of ONE of the following:</p> <ul style="list-style-type: none"> <li>• Gallbladder Cancer</li> <li>• Intrahepatic cholangiocarcinoma</li> <li>• Extrahepatic cholangiocarcinoma</li> </ul> <p><b>AND</b></p> <p><b>2 -</b> Disease is human epidermal growth factor receptor 2 (HER2)-positive</p> |                       |

**AND**

**3** - Disease is ONE of the following:

- Unresectable
- Resected gross residual (R2)
- Metastatic

**AND**

**4** - Patient has received at least one prior systemic therapy

**AND**

**5** - Used in combination with trastuzumab (e.g., Kanjinti, Ogivri, Trazimera)

|                                                                                                                      |                                                                     |
|----------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------|
| Product Name:Tukysa                                                                                                  |                                                                     |
| Diagnosis                                                                                                            | Breast Cancer, CNS Cancers, Colorectal Cancer, Biliary Tract Cancer |
| Approval Length                                                                                                      | 12 month(s)                                                         |
| Therapy Stage                                                                                                        | Reauthorization                                                     |
| Guideline Type                                                                                                       | Prior Authorization                                                 |
| <b>Approval Criteria</b><br><b>1</b> - Patient does not show evidence of progressive disease while on Tukysa therapy |                                                                     |

|                     |                           |
|---------------------|---------------------------|
| Product Name:Tukysa |                           |
| Diagnosis           | NCCN Recommended Regimens |
| Approval Length     | 12 month(s)               |
| Therapy Stage       | Initial Authorization     |
| Guideline Type      | Prior Authorization       |

**Approval Criteria**

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

|                                                                                                          |                           |
|----------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Tukysa                                                                                      |                           |
| Diagnosis                                                                                                | NCCN Recommended Regimens |
| Approval Length                                                                                          | 12 month(s)               |
| Therapy Stage                                                                                            | Reauthorization           |
| Guideline Type                                                                                           | Prior Authorization       |
| <p><b>Approval Criteria</b></p> <p>1 - Documentation of positive clinical response to Tukysa therapy</p> |                           |

## 2 . Revision History

| Date      | Notes                                                 |
|-----------|-------------------------------------------------------|
| 7/16/2025 | No clinical changes to guideline. Added IN formulary. |

Turalio



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-161269                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Guideline Name</b> | Turalio                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 1/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                      |                                                                              |
|----------------------|------------------------------------------------------------------------------|
| Product Name:Turalio |                                                                              |
| Diagnosis            | Tenosynovial Giant Cell Tumor (TGCT)/Pigmented Villonodular Synovitis (PVNS) |
| Approval Length      | 12 month(s)                                                                  |
| Therapy Stage        | Initial Authorization                                                        |
| Guideline Type       | Prior Authorization                                                          |

**Approval Criteria**

1 - Patient has a diagnosis of tenosynovial giant cell tumor (TGCT)/pigmented villonodular synovitis (PVNS)

|                                                                                                                                                                                                                                                                                                                                               |                       |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Turalio                                                                                                                                                                                                                                                                                                                          |                       |
| Diagnosis                                                                                                                                                                                                                                                                                                                                     | Histiocytic Neoplasms |
| Approval Length                                                                                                                                                                                                                                                                                                                               | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                 | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                | Prior Authorization   |
| <b>Approval Criteria</b><br><br>1 - Diagnosis of ONE of the following: <ul style="list-style-type: none"> <li>• Langerhans Cell Histiocytosis</li> <li>• Erdheim-Chester Disease</li> <li>• Rosai-Dorfman Disease</li> </ul> <p style="text-align: center;"><b>AND</b></p> 2 - Colony stimulating factor 1 receptor (CSF1R) mutation positive |                       |

|                          |                                                                                                     |
|--------------------------|-----------------------------------------------------------------------------------------------------|
| Product Name:Turalio     |                                                                                                     |
| Diagnosis                | Tenosynovial Giant Cell Tumor (TGCT)/Pigmented Villonodular Synovitis (PVNS), Histiocytic Neoplasms |
| Approval Length          | 12 month(s)                                                                                         |
| Therapy Stage            | Reauthorization                                                                                     |
| Guideline Type           | Prior Authorization                                                                                 |
| <b>Approval Criteria</b> |                                                                                                     |

1 - Patient does not show evidence of progressive disease while on Turalio therapy

| Product Name:Turalio                                                                                                                    |                           |
|-----------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Diagnosis                                                                                                                               | NCCN Recommended Regimens |
| Approval Length                                                                                                                         | 12 month(s)               |
| Therapy Stage                                                                                                                           | Initial Authorization     |
| Guideline Type                                                                                                                          | Prior Authorization       |
| <b>Approval Criteria</b><br><br>1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium |                           |

| Product Name:Turalio                                                                               |                           |
|----------------------------------------------------------------------------------------------------|---------------------------|
| Diagnosis                                                                                          | NCCN Recommended Regimens |
| Approval Length                                                                                    | 12 month(s)               |
| Therapy Stage                                                                                      | Reauthorization           |
| Guideline Type                                                                                     | Prior Authorization       |
| <b>Approval Criteria</b><br><br>1 - Documentation of positive clinical response to Turalio therapy |                           |

## 2 . Revision History

| Date       | Notes        |
|------------|--------------|
| 11/25/2024 | Updated GPIs |

Tykerb



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-161408                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Guideline Name</b> | Tykerb                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 1/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                                              |                       |
|----------------------------------------------|-----------------------|
| Product Name:Brand Tykerb, generic lapatinib |                       |
| Diagnosis                                    | Breast Cancer         |
| Approval Length                              | 12 month(s)           |
| Therapy Stage                                | Initial Authorization |
| Guideline Type                               | Prior Authorization   |



**Approval Criteria**

**1** - ALL of the following:

**1.1** Diagnosis of recurrent unresectable (local or regional) or stage IV breast cancer

**AND**

**1.2** Disease is hormone receptor positive and human epidermal growth factor receptor 2-positive (HER2+)

**AND**

**1.3** Used in combination with an aromatase inhibitor [e.g., Aromasin (exemestane), Femara (letrozole), Arimidex (anastrozole)]

**OR**

**2** - ALL of the following:

**2.1** ONE of the following:

- Diagnosis of recurrent unresectable (local or regional) or stage IV breast cancer
- Breast cancer that is unresponsive to preoperative systemic therapy

**AND**

**2.2** Disease is HER2+

**AND**

**2.3** Used as fourth line therapy and beyond in combination with ONE of the following:

- Herceptin (trastuzumab)

- Xeloda (capecitabine)

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                      |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|
| Product Name: Brand Tykerb, generic lapatinib                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                      |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Central Nervous System (CNS) Cancers |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | 12 month(s)                          |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Initial Authorization                |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Prior Authorization                  |
| <p><b>Approval Criteria</b></p> <p><b>1 - ALL of the following:</b></p> <p><b>1.1</b> Diagnosis of recurrent, central nervous system (CNS) cancer with metastatic lesions</p> <p style="text-align: center;"><b>AND</b></p> <p><b>1.2</b> Tykerb is active against primary (breast) tumor</p> <p style="text-align: center;"><b>AND</b></p> <p><b>1.3</b> Used in combination with Xeloda (capecitabine)</p> <p style="text-align: center;"><b>OR</b></p> <p><b>2 - ALL of the following:</b></p> <p><b>2.1</b> Diagnosis of progressive or recurrent intracranial or spinal ependymoma (excluding subependymoma)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2.2</b> Patient has received previous radiation therapy</p> |                                      |

**AND**

**2.3 ONE of the following:**

- Patient has received gross total or subtotal resection with negative cerebrospinal fluid (CSF) cytology
- Patient has received subtotal resection and evidence of metastasis (brain, spine, or CSF)
- Patient has unresectable disease

**AND**

**2.4 Used in combination with Temodar (temozolomide)**

|                                                                                                                                                                                                             |                       |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Brand Tykerb, generic lapatinib                                                                                                                                                                |                       |
| Diagnosis                                                                                                                                                                                                   | Chordoma              |
| Approval Length                                                                                                                                                                                             | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                               | Initial Authorization |
| Guideline Type                                                                                                                                                                                              | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of recurrent conventional or chondroid chordoma</p> <p><b>AND</b></p> <p><b>2</b> - Disease is epidermal growth factor receptor (EGFR)-positive</p> |                       |

|                                              |                       |
|----------------------------------------------|-----------------------|
| Product Name:Brand Tykerb, generic lapatinib |                       |
| Diagnosis                                    | Colon Cancer          |
| Approval Length                              | 12 month(s)           |
| Therapy Stage                                | Initial Authorization |

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Prior Authorization |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1 - Diagnosis of colon cancer</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>2 - Disease is human epidermal growth factor receptor 2 (HER2)-amplified and RAS and BRAF wild type</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>3 - ONE of the following:</b></p> <p><b>3.1 Disease is proficient mismatch repair/microsatellite-stable (pMMR/MSS)</b></p> <p style="text-align: center;"><b>OR</b></p> <p><b>3.2 BOTH of the following:</b></p> <p><b>3.2.1 Disease is positive for deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) or polymerase epsilon/delta (POLE/POLD1) mutation</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>3.2.2 ONE of the following:</b></p> <ul style="list-style-type: none"> <li>• Patient is ineligible for or progressed on checkpoint inhibitor immunotherapy [e.g., Opdivo (nivolumab), Keytruda (pembrolizumab), Jemperli (dostarlimab-gxly)]</li> <li>• Patient has a contraindication to checkpoint inhibitor immunotherapy</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>4 - ONE of the following:</b></p> |                     |

**4.1 BOTH of the following:**

- Used as initial therapy for unresectable metachronous metastases
- Previous therapy with FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or CapeOX (capecitabine and oxaliplatin) within the past 12 months

**OR**

**4.2 Intensive chemotherapy with one of the following is not recommended:**

- Oxaliplatin
- Irinotecan
- Capecitabine

**OR**

**4.3 Used as second-line and subsequent therapy for progression of advanced or metastatic disease**

**AND**

**5 - Used in combination with trastuzumab**

**AND**

**6 - Patient has not previously been treated with a HER2 inhibitor [e.g., trastuzumab, Perjeta (pertuzumab), Nerlynx (neratinib)]**

|                                               |                       |
|-----------------------------------------------|-----------------------|
| Product Name: Brand Tykerb, generic lapatinib |                       |
| Diagnosis                                     | Rectal Cancer         |
| Approval Length                               | 12 month(s)           |
| Therapy Stage                                 | Initial Authorization |
| Guideline Type                                | Prior Authorization   |

### **Approval Criteria**

**1** - Diagnosis of rectal cancer

**AND**

**2** - Disease is human epidermal growth factor receptor 2 (HER2)-amplified and RAS and BRAF wild type

**AND**

**3** - ONE of the following:

**3.1** Disease is proficient mismatch repair/microsatellite-stable (pMMR/MSS)

**OR**

**3.2** BOTH of the following:

**3.2.1** Disease is positive for deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) or polymerase epsilon/delta (POLE/POLD1) mutation

**AND**

**3.2.2** ONE of the following:

- Patient is ineligible for or progressed on checkpoint inhibitor immunotherapy [e.g., Opdivo (nivolumab), Keytruda (pembrolizumab), Jemperli (dostarlimab-gxly)]
- Patient has a contraindication to checkpoint inhibitor immunotherapy

**AND**

**4** - ONE of the following:

**4.1** BOTH of the following:

- Used as initial therapy for unresectable metachronous metastases
- Previous therapy with FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or CapeOX (capecitabine and oxaliplatin) within the past 12 months

**OR**

**4.2** Intensive chemotherapy with one of the following is not recommended:

- Oxaliplatin
- Irinotecan
- Capecitabine

**OR**

**4.3** Used as second-line and subsequent therapy for progression of advanced or metastatic disease

**AND**

**5** - Used in combination with trastuzumab

**AND**

**6** - Patient has not previously been treated with a HER2 inhibitor [e.g., trastuzumab, Perjeta (pertuzumab), Nerlynx (neratinib)]

| Product Name:Brand Tykerb, generic lapatinib |                                                                                            |
|----------------------------------------------|--------------------------------------------------------------------------------------------|
| Diagnosis                                    | Breast Cancer, Central Nervous System (CNS) Cancers, Chordoma, Colon Cancer, Rectal Cancer |
| Approval Length                              | 12 month(s)                                                                                |
| Therapy Stage                                | Reauthorization                                                                            |
| Guideline Type                               | Prior Authorization                                                                        |
|                                              |                                                                                            |

**Approval Criteria**

1 - Patient does not show evidence of progressive disease while on Tykerb therapy

Product Name: Brand Tykerb, generic lapatinib

|           |                           |
|-----------|---------------------------|
| Diagnosis | NCCN Recommended Regimens |
|-----------|---------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Brand Tykerb, generic lapatinib

|           |                           |
|-----------|---------------------------|
| Diagnosis | NCCN Recommended Regimens |
|-----------|---------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                 |
|---------------|-----------------|
| Therapy Stage | Reauthorization |
|---------------|-----------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

1 - Documentation of positive clinical response to Tykerb therapy

## 2 . Revision History

| Date       | Notes                                                                                                                  |
|------------|------------------------------------------------------------------------------------------------------------------------|
| 11/28/2024 | Updated coverage criteria for breast cancer, central nervous system cancers, chordoma, colon cancer, and rectal cancer |



Tymlos



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-136548                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Guideline Name</b> | Tymlos                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 1/1/2024 |
|-----------------|----------|

## 1 . Criteria

|                     |                     |
|---------------------|---------------------|
| Product Name:Tymlos |                     |
| Approval Length     | 24 Months*          |
| Guideline Type      | Prior Authorization |
| Approval Criteria   |                     |

**1 - ONE of the following:**

**1.1 BOTH of the following:**

- Patient is female
- Diagnosis of postmenopausal osteoporosis

**OR**

**1.2 BOTH of the following:**

- Patient is male
- Diagnosis of osteoporosis

**AND**

**2 - ONE of the following:**

**2.1** Patient is at high risk of fracture [e.g., recent fracture (e.g., within the past 12 months), fractures while on approved osteoporosis therapy, multiple fractures, fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids), very low T-score (e.g., less than -3.0), high risk for falls or history of injurious falls, and very high fracture probability by FRAX (fracture risk assessment tool) (e.g., major osteoporosis fracture greater than 30%, hip fracture greater than 4.5%)]

**OR**

**2.2** Patient has a history of failure, intolerance, or contraindication to other available osteoporosis therapy (e.g., alendronate, denosumab, risedronate, zoledronate)

**AND**

**3 - Treatment duration has not exceeded a total of 24 months\* of cumulative use of parathyroid hormone analogs (e.g., Teriparatide Injection, Forteo, Tymlos) during the patient's lifetime**

|       |                                                                                                                                                                               |
|-------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Notes | *Duration of coverage will be limited to 24 months of cumulative parathyroid hormone analog therapy (e.g., Teriparatide Injection, Forteo, Tymlos) in the patient's lifetime. |
|-------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

## 2 . Revision History

| Date       | Notes                                                                                                        |
|------------|--------------------------------------------------------------------------------------------------------------|
| 11/20/2023 | Updated criteria to align with label and treatment guidelines, removed routine audit language from criteria. |

Upneeq



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-208217                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Guideline Name</b> | Upneeq                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Arizona (ACUAZ, ACUAZEC)</li> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania (ACUPA)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 3/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                     |                       |
|---------------------|-----------------------|
| Product Name:Upneeq |                       |
| Approval Length     | 12 month(s)           |
| Therapy Stage       | Initial Authorization |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                     |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of acquired blepharoptosis</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Patient has a functional impairment related to the position of the eyelid</p> <p style="text-align: center;"><b>AND</b></p> <p>3 - ONE of the following:</p> <ul style="list-style-type: none"> <li>• Marginal reflex distance-1 (MRD-1) is less than or equal to 2 millimeters (mm) in primary gaze</li> <li>• Marginal reflex distance-1 (MRD-1) is less than or equal to 2 mm in down gaze</li> <li>• Superior visual field loss of at least 12 degrees or 24 percent</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p>4 - Other treatable causes of blepharoptosis have been ruled out (e.g., recent botulinum toxin injections, myasthenia gravis)</p> |                     |

|                                                                                                     |                     |
|-----------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Upneeq                                                                                 |                     |
| Approval Length                                                                                     | 12 month(s)         |
| Therapy Stage                                                                                       | Reauthorization     |
| Guideline Type                                                                                      | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p>1 - Documentation of a positive clinical response to therapy</p> |                     |

## 2 . Revision History

| Date     | Notes                                                 |
|----------|-------------------------------------------------------|
| 3/5/2025 | Added PA-CAID for 4/1 go-live. No change to criteria. |

Ustekinumab



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-427222                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Guideline Name</b> | Ustekinumab                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 11/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                                                                                                                                                                  |                                                                                                                                                                                           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Product Name: All subcutaneous formulations of the following: Stelara, Imuldosa, Otulfi, Pyzchiva, Selarsdi, Steqeyma, Ustekinumab, Wezlana, Yesintek, Starjemza |                                                                                                                                                                                           |
| Diagnosis                                                                                                                                                        | Plaque Psoriasis                                                                                                                                                                          |
| Approval Length                                                                                                                                                  | 12 month(s) NOTE: If approving a non-preferred ustekinumab, please enter: 1) The group authorization CSPREFUSTE and 2) An authorization for the non-preferred ustekinumab at GPI-12 level |
| Therapy Stage                                                                                                                                                    | Initial Authorization                                                                                                                                                                     |
| Guideline Type                                                                                                                                                   | Prior Authorization                                                                                                                                                                       |

## **Approval Criteria**

**1** - ALL of the following:

**1.1** Diagnosis of chronic moderate to severe plaque psoriasis

**AND**

**1.2** ONE of the following:

**1.2.1** ALL of the following:

**1.2.1.1** Greater than or equal to 3% body surface area involvement, palmoplantar, facial, or genital involvement, or severe scalp psoriasis

**AND**

**1.2.1.2** ONE of the following:

**1.2.1.2.1** Failure to ONE of the following topical therapy classes, confirmed by claims history or submitted medical records:

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin
- Coal tar

**OR**

**1.2.1.2.2** History of intolerance or contraindication to ALL of the following topical therapy classes (please specify intolerance or contraindication):

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin



- Coal tar

**AND**

**1.2.1.3 ONE of the following:**

- Failure to a 3 month trial of methotrexate at maximally indicated dose, confirmed by claims history or submitted medical records
- History of intolerance or contraindication to methotrexate (please specify intolerance or contraindication)

**OR**

**1.2.2** Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of plaque psoriasis as confirmed by claims history or submission of medical records [e.g., Cimzia (certolizumab), adalimumab, Otezla (apremilast), Skyrizi (risankizumab-rzaa), Tremfya (guselkumab)]

**AND**

**1.3 ONE of the following:**

- Failure to one of the preferred adalimumab products confirmed by claims history or submitted medical records
- History of intolerance or contraindication to one of the preferred adalimumab products (please specify intolerance or contraindication)

**AND**

**1.4** Patient is NOT receiving ustekinumab in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

**AND**

**1.5 ONE of the following:**

**1.5.1** Requested medication is ustekinumab 45 mg (milligrams)/0.5 mL (milliliters)

**OR**

**1.5.2** BOTH of the following:

- Requested medication is ustekinumab 90 mg/1 mL
- Patient's weight is greater than 100 kilograms (220 pounds)

**AND**

**1.6** Prescribed by or in consultation with a dermatologist

**AND**

**1.7** If the request is for a non-preferred ustekinumab product, the prescriber has given a clinical reason or special circumstance why the patient is unable to use the preferred ustekinumab products (please document reason/special circumstances)\*

**AND**

**1.8** If the request is for Brand Stelara, ONE of the following:

**1.8.1** Submission of medical records confirming patient allergy or intolerance to at least two preferred ustekinumab biosimilars' inactive ingredients\*

**OR**

**1.8.2** BOTH of the following:

- Submission of medical records confirming patient has previously been successfully treated with brand Stelara
- Submission of medical records confirming patient has tried at least two preferred ustekinumab biosimilars for 6-8 weeks per product and saw a decrease in effectiveness\*

**OR**

**2** - ALL of the following:

**2.1** Patient is currently on ustekinumab therapy as confirmed by claims history or submitted medical records

**AND**

**2.2** Diagnosis of chronic moderate to severe plaque psoriasis

**AND**

**2.3** Patient is NOT receiving ustekinumab in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

**AND**

**2.4** Prescribed by or in consultation with a dermatologist

**AND**

**2.5** If the request is for a non-preferred ustekinumab product, the prescriber has given a clinical reason or special circumstance why the patient is unable to use the preferred ustekinumab products (please document reason/special circumstances)\*

**AND**

**2.6** If the request is for Brand Stelara, ONE of the following:

**2.6.1** Submission of medical records confirming patient allergy or intolerance to at least two preferred ustekinumab biosimilars' inactive ingredients\*

**OR**

**2.6.2 BOTH of the following:**

- Submission of medical records confirming patient has previously been successfully treated with brand Stelara
- Submission of medical records confirming patient has tried at least two preferred ustekinumab biosimilars for 6-8 weeks per product and saw a decrease in effectiveness\*

Notes

\*See PDL links in Background

Product Name: All subcutaneous formulations of the following: Stelara, Imuldosa, Otulfi, Pyzchiva, Selarsdi, Steqeyma, Ustekinumab, Wezlana, Yesintek, Starjemza

|                 |                                                                                                                                                                                           |
|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Diagnosis       | Psoriatic Arthritis                                                                                                                                                                       |
| Approval Length | 12 month(s) NOTE: If approving a non-preferred ustekinumab, please enter: 1) The group authorization CSPREFUSTE and 2) An authorization for the non-preferred ustekinumab at GPI-12 level |
| Therapy Stage   | Initial Authorization                                                                                                                                                                     |
| Guideline Type  | Prior Authorization                                                                                                                                                                       |

**Approval Criteria**

**1 - ALL of the following:**

**1.1 ONE of the following:**

**1.1.1 BOTH of the following:**

- Requested medication is ustekinumab 45 mg (milligrams)/0.5 mL (milliliters)
- Diagnosis of active psoriatic arthritis

**OR**

**1.1.2 ALL of the following:**

- Requested medication is ustekinumab 90 mg/1 mL

- Patient's weight is greater than 100 kilograms (220 pounds)
- Diagnosis of active psoriatic arthritis
- Diagnosis of co-existent moderate to severe plaque psoriasis

**AND**

**1.2** Patient is NOT receiving ustekinumab in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

**AND**

**1.3** ONE of the following:

- Failure to a 3 month trial of methotrexate at maximally indicated dose, confirmed by claims history or submitted medical records
- History of intolerance or contraindication to methotrexate (please specify intolerance or contraindication)
- Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of psoriatic arthritis as confirmed by claims history or submission of medical records [e.g., Cimzia (certolizumab), adalimumab, Simponi (golimumab), Tremfya (guselkumab) Xeljanz (tofacitinib), Otezla (apremilast), Rinvoq (upadacitinib)]

**AND**

**1.4** ONE of the following:

- Failure to one of the preferred adalimumab products confirmed by claims history or submitted medical records
- History of intolerance or contraindication to one of the preferred adalimumab products (please specify intolerance or contraindication)

**AND**

**1.5** Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Dermatologist

**AND**

**1.6** If the request is for a non-preferred ustekinumab product, the prescriber has given a clinical reason or special circumstance why the patient is unable to use the preferred ustekinumab products (please document reason/special circumstances)\*

**AND**

**1.7** If the request is for Brand Stelara, ONE of the following:

**1.7.1** Submission of medical records confirming patient allergy or intolerance to at least two preferred ustekinumab biosimilars' inactive ingredients\*

**OR**

**1.7.2** BOTH of the following:

- Submission of medical records confirming patient has previously been successfully treated with brand Stelara
- Submission of medical records confirming patient has tried at least two preferred ustekinumab biosimilars for 6-8 weeks per product and saw a decrease in effectiveness\*

**OR**

**2** - ALL of the following:

**2.1** Patient is currently on ustekinumab therapy as confirmed by claims history or submitted medical records

**AND**

**2.2** Diagnosis of active psoriatic arthritis

**AND**

**2.3** Patient is NOT receiving ustekinumab in combination with another targeted

immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

**AND**

**2.4** Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Dermatologist

**AND**

**2.5** If the request is for a non-preferred ustekinumab product, the prescriber has given a clinical reason or special circumstance why the patient is unable to use the preferred ustekinumab products (please document reason/special circumstances)\*

**AND**

**2.6** If the request is for Brand Stelara, ONE of the following:

**2.6.1** Submission of medical records confirming patient allergy or intolerance to at least two preferred ustekinumab biosimilars' inactive ingredients\*

**OR**

**2.6.2** BOTH of the following:

- Submission of medical records confirming patient has previously been successfully treated with brand Stelara
- Submission of medical records confirming patient has tried at least two preferred ustekinumab biosimilars for 6-8 weeks per product and saw a decrease in effectiveness\*

Notes

\*See PDL links in Background

Product Name: All subcutaneous formulations of the following: Stelara, Imuldosa, Otulfi, Pyzchiva, Selarsdi, Steqeyma, Ustekinumab, Wezlana, Yesintek, Starjemza

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                                           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Plaque Psoriasis, Psoriatic Arthritis                                                                                                                                                     |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 12 month(s) NOTE: If approving a non-preferred ustekinumab, please enter: 1) The group authorization CSPREFUSTE and 2) An authorization for the non-preferred ustekinumab at GPI-12 level |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Reauthorization                                                                                                                                                                           |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Prior Authorization                                                                                                                                                                       |
| <p><b>Approval Criteria</b></p> <p><b>1 - Documentation of positive clinical response to ustekinumab therapy</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>2 - Patient is NOT receiving ustekinumab in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]*</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>3 - If the request is for a non-preferred ustekinumab product, the prescriber has given a clinical reason or special circumstance why the patient is unable to use the preferred ustekinumab products (please document reason/special circumstances)**</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>4 - If the request is for Brand Stelara, ONE of the following:</b></p> <p><b>4.1 Submission of medical records confirming patient allergy or intolerance to at least two preferred ustekinumab biosimilars' inactive ingredients**</b></p> <p style="text-align: center;"><b>OR</b></p> <p><b>4.2 BOTH of the following:</b></p> |                                                                                                                                                                                           |



|                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"> <li>• Submission of medical records confirming patient has previously been successfully treated with brand Stelara</li> <li>• Submission of medical records confirming patient has tried at least two preferred ustekinumab biosimilars for 6-8 weeks per product and saw a decrease in effectiveness**</li> </ul> |                                                                                                                           |
| Notes                                                                                                                                                                                                                                                                                                                                                 | <p>*Examples of drug(s) may not be applicable based on the requested indication.</p> <p>**See PDL links in Background</p> |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Product Name: 90 mg/mL subcutaneous formulation of the following: Stelara, Imuldosa, Otulfi, Pyzchiva, Selarsdi, Steqeyma, Ustekinumab, Wezlana, Yesintek, Starjemza                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                           |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Crohn's Disease (CD)                                                                                                                                                                      |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 12 month(s) NOTE: If approving a non-preferred ustekinumab, please enter: 1) The group authorization CSPREFUSTE and 2) An authorization for the non-preferred ustekinumab at GPI-12 level |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Initial Authorization                                                                                                                                                                     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Prior Authorization                                                                                                                                                                       |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of moderately to severely active Crohn's disease</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - ONE of the following:</p> <p>2.1 BOTH of the following:</p> <p>2.1.1 ONE of the following:</p> <p>2.1.1.1 Failure to ONE of the following conventional therapy drugs or classes at maximally indicated dose, confirmed by claims history or submitted medical records:</p> <ul style="list-style-type: none"> <li>• Corticosteroids (e.g., prednisone, methylprednisolone, budesonide)</li> <li>• 6-mercaptopurine (Purinethol)</li> <li>• Azathioprine (Imuran)</li> <li>• Methotrexate (Rheumatrex, Trexall)</li> </ul> |                                                                                                                                                                                           |

**OR**

**2.1.1.2** History of intolerance or contraindication to ALL of the following conventional therapy drugs or classes (please specify intolerance or contraindication):

- Corticosteroids (e.g., prednisone, methylprednisolone, budesonide)
- 6-mercaptopurine (Purinethol)
- Azathioprine (Imuran)
- Methotrexate (Rheumatrex, Trexall)

**OR**

**2.1.1.3** Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of Crohn's disease as confirmed by claims history or submission of medical records [e.g., Cimzia (certolizumab), adalimumab]

**AND**

**2.1.2** ONE of the following:

- Failure to one of the preferred adalimumab products, as confirmed by claims history or submitted medical records
- History of intolerance or contraindication to one of the preferred adalimumab products (please specify intolerance or contraindication)

**OR**

**2.2** Patient is currently on ustekinumab therapy for moderately to severely active Crohn's disease as confirmed by claims history or submitted medical records

**OR**

**2.3** Patient has been established on therapy with ustekinumab under an active UnitedHealthcare medical benefit prior authorization for treatment of moderately to severely active Crohn's disease

**AND**

**3** - Patient is NOT receiving ustekinumab in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Skyrizi (risankizumab)]

**AND**

**4** - Prescribed by or in consultation with a gastroenterologist

**AND**

**5** - If the request is for a non-preferred ustekinumab product, the prescriber has given a clinical reason or special circumstance why the patient is unable to use the preferred ustekinumab products (please document reason/special circumstances)\*

**AND**

**6** - If the request is for Brand Stelara, ONE of the following:

**6.1** Submission of medical records confirming patient allergy or intolerance to at least two preferred ustekinumab biosimilars' inactive ingredients\*

**OR**

**6.2** BOTH of the following:

- Submission of medical records confirming patient has previously been successfully treated with brand Stelara
- Submission of medical records confirming patient has tried at least two preferred ustekinumab biosimilars for 6-8 weeks per product and saw a decrease in effectiveness\*

Notes

\*See PDL links in Background

Product Name: 90 mg/mL subcutaneous formulation of the following: Stelara, Imuldosa, Otulfi, Pyzchiva, Selarsdi, Steqeyma, Ustekinumab, Wezlana, Yesintek, Starjemza

Diagnosis

Ulcerative Colitis

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 12 month(s) NOTE: If approving a non-preferred ustekinumab, please enter: 1) The group authorization CSPREFUSTE and 2) An authorization for the non-preferred ustekinumab at GPI-12 level |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Initial Authorization                                                                                                                                                                     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Prior Authorization                                                                                                                                                                       |
| <p><b>Approval Criteria</b></p> <p><b>1 - Diagnosis of moderately to severely active ulcerative colitis</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>2 - ONE of the following:</b></p> <p><b>2.1 BOTH of the following:</b></p> <p><b>2.1.1 ONE of the following:</b></p> <ul style="list-style-type: none"> <li>• Patient has had prior or concurrent inadequate response to a therapeutic course of oral corticosteroids and/or immunosuppressants (e.g., azathioprine, 6-mercaptopurine), as confirmed by claims history or submitted medical records</li> <li>• Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of ulcerative colitis as confirmed by claims history or submission of medical records [e.g., adalimumab, Simponi (golimumab), Xeljanz (tofacitinib)]</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>2.1.2 ONE of the following:</b></p> <ul style="list-style-type: none"> <li>• Failure to one of the preferred adalimumab products, confirmed by claims history or submitted medical records</li> <li>• History of intolerance or contraindication to one of the preferred adalimumab products (please specify intolerance or contraindication)</li> </ul> <p style="text-align: center;"><b>OR</b></p> <p><b>2.2 Patient is currently on ustekinumab therapy for moderately to severely active ulcerative colitis as confirmed by claims history or submitted medical records</b></p> |                                                                                                                                                                                           |

**OR**

**2.3** Patient has been established on therapy with ustekinumab under an active UnitedHealthcare medical benefit prior authorization for treatment of moderately to severely active ulcerative colitis

**AND**

**3** - Patient is NOT receiving ustekinumab in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Skyrizi (risankizumab)]

**AND**

**4** - Prescribed by or in consultation with a gastroenterologist

**AND**

**5** - If the request is for a non-preferred ustekinumab product, the prescriber has given a clinical reason or special circumstance why the patient is unable to use the preferred ustekinumab products (please document reason/special circumstances)\*

**AND**

**6** - If the request is for Brand Stelara, ONE of the following:

**6.1** Submission of medical records confirming patient allergy or intolerance to at least two preferred ustekinumab biosimilars' inactive ingredients\*

**OR**

**6.2** BOTH of the following:

- Submission of medical records confirming patient has previously been successfully treated with brand Stelara

- Submission of medical records confirming patient has tried at least two preferred ustekinumab biosimilars for 6-8 weeks per product and saw a decrease in effectiveness\*

Notes

\*See PDL links in Background

Product Name:90 mg/mL subcutaneous formulation of the following: Stelara, Imuldosa, Otulfi, Pyzchiva, Selarsdi, Steqeyma, Ustekinumab, Wezlana, Yesintek, Starjemza

|                 |                                                                                                                                                                                           |
|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Diagnosis       | Crohn's Disease (CD), Ulcerative Colitis                                                                                                                                                  |
| Approval Length | 12 month(s) NOTE: If approving a non-preferred ustekinumab, please enter: 1) The group authorization CSPREFUSTE and 2) An authorization for the non-preferred ustekinumab at GPI-12 level |
| Therapy Stage   | Reauthorization                                                                                                                                                                           |
| Guideline Type  | Prior Authorization                                                                                                                                                                       |

### Approval Criteria

1 - Documentation of positive clinical response to ustekinumab therapy

**AND**

2 - Patient is NOT receiving ustekinumab in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Skyrizi (risankizumab)]

**AND**

3 - If the request is for a non-preferred ustekinumab product, the prescriber has given a clinical reason or special circumstance why the patient is unable to use the preferred ustekinumab products (please document reason/special circumstances)\*

**AND**

4 - If the request is for Brand Stelara, ONE of the following:

**4.1** Submission of medical records confirming patient allergy or intolerance to at least two preferred ustekinumab biosimilars' inactive ingredients\*

**OR**

**4.2** BOTH of the following:

- Submission of medical records confirming patient has previously been successfully treated with brand Stelara
- Submission of medical records confirming patient has tried at least two preferred ustekinumab biosimilars for 6-8 weeks per product and saw a decrease in effectiveness\*

Notes

\*See PDL links in Background

## 2 . Background

### Benefit/Coverage/Program Information

#### PDL Links

CO: <https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html>

HI: <https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html>

MD: <https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-cp-pharmacy.html>

NJ: <https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html>

NM: <https://www.uhcprovider.com/en/health-plans-by-state/new-mexico-health-plans/nm-comm-plan-home/nm-cp-pharmacy.html>

NY: <https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html>

PA: <https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP>

RI: <https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html>

### 3 . Revision History

| Date       | Notes                          |
|------------|--------------------------------|
| 10/24/2025 | Updated GPIs. Added Starjemza. |



Vafseo



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-435206                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Guideline Name</b> | Vafseo                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Pennsylvania (ACUPA)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Washington (ACUWA, ACUWAAHE, ACUWAC)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 12/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                     |             |
|---------------------|-------------|
| Product Name:Vafseo |             |
| Approval Length     | 12 month(s) |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                       |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1 - Diagnosis of anemia due to chronic kidney disease (CKD)</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>2 - Patient has been receiving dialysis for at least three months</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>3 - BOTH of the following:</b></p> <ul style="list-style-type: none"> <li>• Ferritin greater than 100 mcg/L</li> <li>• Transferrin saturation (TSAT) greater than 20%</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>4 - Hemoglobin level less than 11 g/dL</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>5 - ONE of the following:</b></p> <p><b>5.1</b> Failure to an erythropoietin stimulating agent (ESA) [e.g., Aranesp (darbepoetin), Epogen (epoetin alfa), Procrit (epoetin alfa), Retacrit (epoetin alfa-epbx)] as confirmed by claims history or submission of medical records</p> <p style="text-align: center;"><b>OR</b></p> <p><b>5.2</b> History of contraindication or intolerance to an erythropoietin stimulating agent (ESA) [e.g., Aranesp (darbepoetin), Epogen (epoetin alfa), Procrit (epoetin alfa), Retacrit (epoetin alfa-epbx)] (please specify contraindication or intolerance)</p> |                       |

**AND**

**6** - Prescribed by or in consultation with ONE of the following:

- Hematologist
- Nephrologist

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                     |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Vafseo                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                     |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | 12 month(s)         |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of positive clinical response to Vafseo therapy (e.g., clinically meaningful increase in hemoglobin level)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Adequate iron stores confirmed by BOTH of the following:</p> <ul style="list-style-type: none"> <li>• Ferritin greater than 100 mcg/L</li> <li>• Transferrin saturation (TSAT) greater than 20%</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Hemoglobin level does not exceed 11 g/dL</p> <p style="text-align: center;"><b>AND</b></p> <p><b>4</b> - Patient is not on concurrent treatment with an erythropoietin stimulating agent (ESA) [e.g., Aranesp (darbepoetin), Epogen (epoetin alfa), Procrit (epoetin alfa), Retacrit (epoetin alfa-epbx)]</p> |                     |

**AND**

**5** - Prescribed by or in consultation with ONE of the following:

- Hematologist
- Nephrologist

## **2 . Revision History**

| Date       | Notes                                                                              |
|------------|------------------------------------------------------------------------------------|
| 10/28/2025 | Combined formularies. Updated hemoglobin reauth criterion. Minor cosmetic updates. |

Valchlor



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-117472                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Guideline Name</b> | Valchlor                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 1/1/2023 |
|-----------------|----------|

## 1 . Criteria

|                       |                             |
|-----------------------|-----------------------------|
| Product Name:Valchlor |                             |
| Diagnosis             | Primary Cutaneous Lymphomas |
| Approval Length       | 12 month(s)                 |
| Therapy Stage         | Initial Authorization       |
| Guideline Type        | Prior Authorization         |

### Approval Criteria

1 - Diagnosis of ONE of the following:

- Chronic or smoldering T-cell leukemia/lymphoma
- Primary cutaneous marginal zone or follicle center B-cell lymphoma
- Lymphomatoid papulosis (LyP) with extensive lesions
- Mycosis fungoides (MF)/Sezary syndrome (SS)

Product Name:Valchlor

|                 |                       |
|-----------------|-----------------------|
| Diagnosis       | Histiocytic Neoplasms |
| Approval Length | 12 month(s)           |
| Therapy Stage   | Initial Authorization |
| Guideline Type  | Prior Authorization   |

### Approval Criteria

1 - Diagnosis of Langerhans Cell Histiocytosis (LCH)

**AND**

2 - Skin disease is unifocal and isolated

Product Name:Valchlor

|                 |                                                    |
|-----------------|----------------------------------------------------|
| Diagnosis       | Primary Cutaneous Lymphomas, Histiocytic Neoplasms |
| Approval Length | 12 month(s)                                        |
| Therapy Stage   | Reauthorization                                    |
| Guideline Type  | Prior Authorization                                |

### Approval Criteria

1 - Patient does not show evidence of progressive disease while on Valchlor

| Product Name:Valchlor                                                                                                                   |                           |
|-----------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Diagnosis                                                                                                                               | NCCN Recommended Regimens |
| Approval Length                                                                                                                         | 12 month(s)               |
| Therapy Stage                                                                                                                           | Initial Authorization     |
| Guideline Type                                                                                                                          | Prior Authorization       |
| <b>Approval Criteria</b><br><br>1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium |                           |

| Product Name:Valchlor                                                                               |                           |
|-----------------------------------------------------------------------------------------------------|---------------------------|
| Diagnosis                                                                                           | NCCN Recommended Regimens |
| Approval Length                                                                                     | 12 month(s)               |
| Therapy Stage                                                                                       | Reauthorization           |
| Guideline Type                                                                                      | Prior Authorization       |
| <b>Approval Criteria</b><br><br>1 - Documentation of positive clinical response to Valchlor therapy |                           |

## 2 . Revision History

| Date       | Notes                                                     |
|------------|-----------------------------------------------------------|
| 11/30/2022 | Updated Markets in Scope. No changes to clinical criteria |

Vanflyta



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-435240                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Guideline Name</b> | Vanflyta                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 12/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                       |                        |
|-----------------------|------------------------|
| Product Name:Vanflyta |                        |
| Diagnosis             | Acute Myeloid Leukemia |
| Approval Length       | 12 month(s)            |
| Therapy Stage         | Initial Authorization  |
| Guideline Type        | Prior Authorization    |



**Approval Criteria**

**1** - Diagnosis of acute myeloid leukemia (AML)

**AND**

**2** - Disease is FLT3 internal tandem duplication (ITD) positive

Product Name: Vanflyta

|           |                            |
|-----------|----------------------------|
| Diagnosis | Myeloid/Lymphoid Neoplasms |
|-----------|----------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

**1** - Diagnosis of lymphoid, myeloid, or mixed lineage neoplasms with eosinophilia in the chronic or blast phase

**AND**

**2** - Patient has an FLT3 rearrangement

Product Name: Vanflyta

|           |                                                    |
|-----------|----------------------------------------------------|
| Diagnosis | Acute Myeloid Leukemia, Myeloid/Lymphoid Neoplasms |
|-----------|----------------------------------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                 |
|---------------|-----------------|
| Therapy Stage | Reauthorization |
|---------------|-----------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

1 - Patient does not show evidence of progressive disease while on Vanflyta therapy

**Product Name:Vanflyta**

|           |                           |
|-----------|---------------------------|
| Diagnosis | NCCN Recommended Regimens |
|-----------|---------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

**Product Name:Vanflyta**

|           |                           |
|-----------|---------------------------|
| Diagnosis | NCCN Recommended Regimens |
|-----------|---------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                 |
|---------------|-----------------|
| Therapy Stage | Reauthorization |
|---------------|-----------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

1 - Documentation of positive clinical response to Vanflyta therapy

## 2 . Revision History

| Date      | Notes                                                                                                                   |
|-----------|-------------------------------------------------------------------------------------------------------------------------|
| 11/3/2025 | Combined formularies. Updated AML criteria and added criteria for M yeloid/Lymphoid Neoplasms per NCCN recommendations. |

Vanrafia



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-363213                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Guideline Name</b> | Vanrafia                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Pennsylvania (ACUPA)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 9/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                       |                       |
|-----------------------|-----------------------|
| Product Name:Vanrafia |                       |
| Approval Length       | 12 month(s)           |
| Therapy Stage         | Initial Authorization |

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Prior Authorization |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of primary immunoglobulin A nephropathy (IgAN) confirmed by renal biopsy</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Patient is at risk of disease progression</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Medication is used to slow kidney function decline</p> <p style="text-align: center;"><b>AND</b></p> <p><b>4</b> - Medication is used to reduce proteinuria</p> <p style="text-align: center;"><b>AND</b></p> <p><b>5</b> - Estimated glomerular filtration rate (eGFR) is greater than or equal to 30 mL/min/1.73 m<sup>2</sup></p> <p style="text-align: center;"><b>AND</b></p> <p><b>6</b> - Both of the following:</p> <p><b>6.1</b> Patient is on a maximized stable dose with ONE of the following prior to initiating therapy confirmed by claims history or submitted medical records:</p> <ul style="list-style-type: none"> <li>• Maximally tolerated angiotensin converting enzyme (ACE) inhibitor (e.g., captopril, enalapril)</li> <li>• Maximally tolerated angiotensin II receptor blocker (ARB) (e.g., candesartan, valsartan)</li> </ul> |                     |

**AND**

**6.2** Use of endothelin receptor antagonists [(ERAs) e.g., Letairis, Opsumit, Tracleer]] will be discontinued prior to initiating treatment

**AND**

**7** - One of the following:

**7.1** Failure to a 30-day trial of a glucocorticoid (e.g., methylprednisolone, prednisone) confirmed by claims history or submitted medical records

**OR**

**7.2** History of contraindication or intolerance to a 30-day trial of a glucocorticoid (e.g., methylprednisolone, prednisone) (please specify intolerance or contraindication)

**AND**

**8** - Prescribed by or in consultation with a nephrologist

|                                                                                                                               |                     |
|-------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name: Vanrafia                                                                                                        |                     |
| Approval Length                                                                                                               | 12 month(s)         |
| Therapy Stage                                                                                                                 | Reauthorization     |
| Guideline Type                                                                                                                | Prior Authorization |
| <b>Approval Criteria</b><br><b>1</b> - Documentation of positive clinical response demonstrated by a reduction in proteinuria |                     |

## 2 . Revision History

UnitedHealthcare Community Plan of New Jersey – Clinical Pharmacy Guidelines

| Date      | Notes |
|-----------|-------|
| 8/12/2025 | New   |

Vecamyl



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-135290                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Guideline Name</b> | Vecamyl                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 1/1/2024 |
|-----------------|----------|

### Note:

Effective Date: 11/15/2019

## 1 . Criteria

|                      |                       |
|----------------------|-----------------------|
| Product Name:Vecamyl |                       |
| Approval Length      | 12 month(s)           |
| Therapy Stage        | Initial Authorization |
| Guideline Type       | Prior Authorization   |

**Approval Criteria**

1 - Diagnosis of moderately severe to severe essential hypertension

**OR**

2 - Diagnosis of uncomplicated malignant hypertension

Product Name:Vecamyl

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                 |
|---------------|-----------------|
| Therapy Stage | Reauthorization |
|---------------|-----------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

1 - Documentation of a positive clinical response to Vecamyl therapy

## 2 . Revision History

| Date | Notes |
|------|-------|
|------|-------|

|            |                                                   |
|------------|---------------------------------------------------|
| 10/23/2023 | Combined all Core formularies into one guideline. |
|------------|---------------------------------------------------|



Velsipity



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-208196                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Guideline Name</b> | Velsipity                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 4/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                        |                       |
|------------------------|-----------------------|
| Product Name:Velsipity |                       |
| Approval Length        | 12 month(s)           |
| Therapy Stage          | Initial Authorization |
| Guideline Type         | Prior Authorization   |
|                        |                       |

## **Approval Criteria**

**1** - Diagnosis of moderately to severely active ulcerative colitis (UC)

**AND**

**2** - ONE of the following:

**2.1** Patient has had prior or concurrent inadequate response to a therapeutic course of oral corticosteroids and/or immunosuppressants (e.g., azathioprine, 6-mercaptopurine)

**OR**

**2.2** Patient has been previously treated with a targeted immunomodulator FDA (Food and Drug Administration)-approved for the treatment of ulcerative colitis as confirmed by claims history or submission of medical records [e.g., adalimumab, Simponi (golimumab), ustekinumab, Xeljanz (tofacitinib), Rinvoq (upadacitinib)]

**AND**

**3** - ONE of the following:

**3.1** Patient is currently on Velsipity therapy as confirmed by claims history or submission of medical records

**OR**

**3.2** Failure to ONE of the following as confirmed by claims history or submission of medical records:

- One of the preferred adalimumab products\*
- One of the preferred ustekinumab products\*

**OR**

**3.3** History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- One of the preferred adalimumab products\*

- One of the preferred ustekinumab products\*

**AND**

**4** - Patient is NOT receiving Velsipity in combination with a targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), ustekinumab, Skyrizi (risankizumab), Omvoh (mirikizumab-mrkz), Entyvio (vedolizumab)]

**AND**

**5** - Prescribed by or in consultation with a gastroenterologist

|       |                                                                                    |
|-------|------------------------------------------------------------------------------------|
| Notes | *For a list of preferred adalimumab products please reference drug coverage tools. |
|-------|------------------------------------------------------------------------------------|

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                     |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Velsipity                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                     |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | 12 month(s)         |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of positive clinical response to Velsipity therapy</p> <p><b>AND</b></p> <p><b>2</b> - Patient is NOT receiving Velsipity in combination with a targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), ustekinumab, Skyrizi (risankizumab), Omvoh (mirikizumab-mrkz), Entyvio (vedolizumab)]</p> |                     |

## 2 . Background

| Benefit/Coverage/Program Information                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |  |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
| <b>PDL links:</b><br>CO: <a href="https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html</a><br>HI: <a href="https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html</a><br>MD: <a href="https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-cp-pharmacy.html</a><br>NJ: <a href="https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html</a><br>NM: <a href="https://www.uhcprovider.com/en/health-plans-by-state/new-mexico-health-plans/nm-comm-plan-home/nm-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/new-mexico-health-plans/nm-comm-plan-home/nm-cp-pharmacy.html</a><br>NY: <a href="https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html</a><br>PA CHIP: <a href="https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP">https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP</a><br>RI: <a href="https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html</a> |  |

### 3 . Revision History

| Date     | Notes                                                                                                                                                                        |
|----------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 3/5/2025 | Updated formularies. Updated safety check language. Replaced Stelara with ustekinumab throughout. Added ustekinumab as a step option in UC. Added NM PDL link to background. |

Vemlidy



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-331188                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Guideline Name</b> | Vemlidy                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• </li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 8/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                      |                       |
|----------------------|-----------------------|
| Product Name:Vemlidy |                       |
| Approval Length      | 12 month(s)           |
| Therapy Stage        | Initial Authorization |
| Guideline Type       | Prior Authorization   |

### **Approval Criteria**

**1** - Diagnosis of chronic hepatitis B infection

**AND**

**2** - ONE of the following:

- Failure to entecavir (generic Baraclude) as confirmed by claims history or submission of medical records
- History of contraindication or intolerance to entecavir (generic Baraclude) (please specify contraindication or intolerance)
- Patient is not a suitable candidate for entecavir (generic Baraclude)

**AND**

**3** - ONE of the following:

**3.1** Failure to tenofovir disoproxil fumarate (generic Viread) as confirmed by claims history or submission of medical records

**OR**

**3.2** History of contraindication or intolerance to tenofovir disoproxil fumarate (generic Viread) (please specify contraindication or intolerance)

**OR**

**3.3** Submission of medical records documenting an estimated glomerular filtration rate below 90 mL/min (milliliters/minute)

**OR**

**3.4** Submission of medical records documenting a diagnosis of osteopenia as defined by a BMD (bone mineral density) T-score between -1 and -2.5 (BMD T-score greater than -2.5 and less than or equal to -1) based on BMD measurements from one of the following with

evidence of progressive bone loss on serial DEXA (dual-energy X-ray absorptiometry) scan [Provider must submit patient specific BMD T-scores]:

- Lumbar spine (at least two vertebral bodies)
- Hip (femoral neck, total hip)
- Radius (one-third radius site)

**OR**

**3.5** Submission of medical records documenting a diagnosis of osteoporosis as defined by a BMD T-score less than or equal to -2.5 based on BMD measurements from one of the following [Provider must submit patient specific BMD T-score]:

- Lumbar spine (at least two vertebral bodies)
- Hip (femoral neck, total hip)
- Radius (one-third radius site)

**OR**

**3.6** Submission of medical records documenting a prior low-trauma or non-traumatic fracture

**OR**

**3.7** Patient is less than 20 years of age

|                                                                                                                             |                     |
|-----------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Vemlidy                                                                                                        |                     |
| Approval Length                                                                                                             | 12 month(s)         |
| Therapy Stage                                                                                                               | Reauthorization     |
| Guideline Type                                                                                                              | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p>1 - Documentation of positive clinical response to Vemlidy therapy</p> <p><b>AND</b></p> |                     |

**2** - Patient is not a suitable candidate for entecavir (generic Baraclude) or tenofovir disoproxil fumarate (generic Viread)

## 2 . Revision History

| Date      | Notes                                                                                                                                    |
|-----------|------------------------------------------------------------------------------------------------------------------------------------------|
| 7/14/2025 | Updated formularies. Added reauth criteria. To initial criteria: added diagnosis check and requirement for submission of medical records |



Venclexta



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-260192                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Guideline Name</b> | Venclexta                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 7/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                        |                                                                   |
|------------------------|-------------------------------------------------------------------|
| Product Name:Venclexta |                                                                   |
| Diagnosis              | Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL) |
| Approval Length        | 12 month(s)                                                       |

|                                                                                                                         |                       |
|-------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                                                           | Initial Authorization |
| Guideline Type                                                                                                          | Prior Authorization   |
| <b>Approval Criteria</b><br><b>1 - Diagnosis of chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL)</b> |                       |

|                                                                                                                                                                               |                       |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Venclexta                                                                                                                                                        |                       |
| Diagnosis                                                                                                                                                                     | Mantle Cell Lymphoma  |
| Approval Length                                                                                                                                                               | 12 month(s)           |
| Therapy Stage                                                                                                                                                                 | Initial Authorization |
| Guideline Type                                                                                                                                                                | Prior Authorization   |
| <b>Approval Criteria</b><br><b>1 - Diagnosis of mantle cell lymphoma (MCL)</b><br><br><p style="text-align: center;"><b>AND</b></p> <b>2 - Not used as first line therapy</b> |                       |

|                                                              |                              |
|--------------------------------------------------------------|------------------------------|
| Product Name:Venclexta                                       |                              |
| Diagnosis                                                    | Acute Myeloid Leukemia (AML) |
| Approval Length                                              | 12 month(s)                  |
| Therapy Stage                                                | Initial Authorization        |
| Guideline Type                                               | Prior Authorization          |
| <b>Approval Criteria</b><br><b>1 - ALL of the following:</b> |                              |

**1.1** Diagnosis of newly-diagnosed acute myeloid leukemia (AML)

**AND**

**1.2** ONE of the following:

- Used as treatment induction in candidates for intensive induction therapy
- Used as treatment induction in candidates for lower-intensity induction therapy
- Used as follow-up after induction therapy following response to previous lower intensity therapy with the same regimen
- Used as consolidation therapy as continuation of lower-intensity regimen used for induction

**AND**

**1.3** Used in combination with decitabine, azacitidine, or low-dose cytarabine

**OR**

**2** - ALL of the following:

- Diagnosis of relapsed/refractory acute myeloid leukemia (AML)
- Used as a component of repeating the initial successful induction regimen
- Greater than or equal to 12 months since induction regimen if not administered continuously
- Therapy was not stopped due to development of clinical resistance

**OR**

**3** - ALL of the following:

- Diagnosis of blastic plasmacytoid dendritic cell neoplasm (BPDCN) - acute myeloid leukemia (AML)
- Considered systemic disease and therapy is given as palliative intent
- Patient has low performance and/or nutritional status (i.e., serum albumin less than 3.2 g/dL [grams/deciliter]; not a candidate for intensive remission therapy or Elzonris)
- Venclexta therapy to be given in combination with azacitidine, decitabine, or low-dose cytarabine

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                       |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Venclexta                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                       |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Multiple Myeloma      |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of relapsed or progressive multiple myeloma which has been previously treated</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Patient has t(11;14) translocation</p> <p style="text-align: center;"><b>AND</b></p> <p>3 - Venclexta therapy to be given in combination with ONE of the following:</p> <ul style="list-style-type: none"> <li>• dexamethasone</li> <li>• dexamethasone and daratumumab</li> <li>• dexamethasone and either bortezomib, carfilzomib, or ixazomib</li> </ul> |                       |

|                                                                                                                         |                                    |
|-------------------------------------------------------------------------------------------------------------------------|------------------------------------|
| Product Name:Venclexta                                                                                                  |                                    |
| Diagnosis                                                                                                               | Acute Lymphoblastic Leukemia (ALL) |
| Approval Length                                                                                                         | 12 month(s)                        |
| Therapy Stage                                                                                                           | Initial Authorization              |
| Guideline Type                                                                                                          | Prior Authorization                |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of relapsed/refractory T-cell acute lymphoblastic leukemia (T-ALL)</p> |                                    |

**AND**

**2** - Venclexta therapy to be given in combination with ONE of the following:

- Decitabine
- Hyper-CVAD
- Nelarabine
- Mini hyper-CVD

|                                                                                                                                                                                                                                                                                                                                                                                                |                                        |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------|
| Product Name:Venclexta                                                                                                                                                                                                                                                                                                                                                                         |                                        |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                      | Chronic Myelomonocytic Leukemia (CMML) |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                | 12 month(s)                            |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                  | Initial Authorization                  |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                 | Prior Authorization                    |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of chronic myelomonocytic leukemia (CMML)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Classified as CMML-2 (less than 20% bone marrow blasts or blast equivalents)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Venclexta therapy to be given in combination with azacitidine or decitabine</p> |                                        |

|                        |                       |
|------------------------|-----------------------|
| Product Name:Venclexta |                       |
| Diagnosis              | Hairy Cell Leukemia   |
| Approval Length        | 12 month(s)           |
| Therapy Stage          | Initial Authorization |

| Guideline Type                                                                                                                                                                                                                                                                                                                   | Prior Authorization |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of hairy cell leukemia</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Disease is progressive after relapsed/refractory therapy</p> <p style="text-align: center;"><b>AND</b></p> <p>3 - Disease is resistant to BRAF inhibitor therapy (i.e., Zelboraf, Tafenlar)</p> |                     |

|                                                                                                                                                                                                                                                                                                                                                                                     |                                                     |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------|
| Product Name: Venclexta                                                                                                                                                                                                                                                                                                                                                             |                                                     |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                           | Accelerated/Blast Phase Myeloproliferative Neoplasm |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                     | 12 month(s)                                         |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                       | Initial Authorization                               |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                      | Prior Authorization                                 |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of accelerated/blast phase myeloproliferative neoplasm</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Used for management of disease progression of myeloproliferative neoplasm</p> <p style="text-align: center;"><b>AND</b></p> <p>3 - Venclexta therapy to be given in combination with azacitidine or decitabine</p> |                                                     |

|                                                                                                                                                                                                          |                                  |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|
| Product Name:Venclexta                                                                                                                                                                                   |                                  |
| Diagnosis                                                                                                                                                                                                | Systemic Light Chain Amyloidosis |
| Approval Length                                                                                                                                                                                          | 12 month(s)                      |
| Therapy Stage                                                                                                                                                                                            | Initial Authorization            |
| Guideline Type                                                                                                                                                                                           | Prior Authorization              |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of relapsed/refractory systemic light chain amyloidosis</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Patient has t(11;14) translocation</p> |                                  |

|                                                                                                                                                    |                                                          |
|----------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------|
| Product Name:Venclexta                                                                                                                             |                                                          |
| Diagnosis                                                                                                                                          | Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma |
| Approval Length                                                                                                                                    | 12 month(s)                                              |
| Therapy Stage                                                                                                                                      | Initial Authorization                                    |
| Guideline Type                                                                                                                                     | Prior Authorization                                      |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of Waldenstrom macroglobulinemia/lymphoplasmacytic lymphoma which has been previously treated</p> |                                                          |

|                        |                           |
|------------------------|---------------------------|
| Product Name:Venclexta |                           |
| Diagnosis              | Myelodysplastic Syndromes |
| Approval Length        | 12 month(s)               |
| Therapy Stage          | Initial Authorization     |
| Guideline Type         | Prior Authorization       |

**Approval Criteria**

**1** - Disease is higher risk (IPSS-R Intermediate, High, or Very High)

**AND**

**2** - Used as initial treatment

**AND**

**3** - Used in combination with azacitidine or decitabine

**Product Name:Venclexta**

|                 |                                                  |
|-----------------|--------------------------------------------------|
| Diagnosis       | All Indications except NCCN Recommended Regimens |
| Approval Length | 12 month(s)                                      |
| Therapy Stage   | Reauthorization                                  |
| Guideline Type  | Prior Authorization                              |

**Approval Criteria**

**1** - Patient does not show evidence of progressive disease while on Venclexta therapy

**Product Name:Venclexta**

|                 |                           |
|-----------------|---------------------------|
| Diagnosis       | NCCN Recommended Regimens |
| Approval Length | 12 month(s)               |
| Therapy Stage   | Initial Authorization     |
| Guideline Type  | Prior Authorization       |

**Approval Criteria**



1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

| Product Name: Venclexta                                                                              |                           |
|------------------------------------------------------------------------------------------------------|---------------------------|
| Diagnosis                                                                                            | NCCN Recommended Regimens |
| Approval Length                                                                                      | 12 month(s)               |
| Therapy Stage                                                                                        | Reauthorization           |
| Guideline Type                                                                                       | Prior Authorization       |
| <b>Approval Criteria</b><br><br>1 - Documentation of positive clinical response to Venclexta therapy |                           |

## 2 . Revision History

| Date      | Notes                                                                                                                                                                                 |
|-----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 5/12/2025 | Updated formularies. Minor formatting changes. Added criteria for Myelodysplastic Syndromes. Updated multiple myeloma criteria to include additional drugs to be given in combination |

Veozah



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-163756                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Guideline Name</b> | Veozah                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 2/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                     |                       |
|---------------------|-----------------------|
| Product Name:Veozah |                       |
| Approval Length     | 12 month(s)           |
| Therapy Stage       | Initial Authorization |
| Guideline Type      | Prior Authorization   |
|                     |                       |

## Approval Criteria

**1** - Diagnosis of moderate to severe vasomotor symptoms due to menopause

**AND**

**2** - One of the following:

**2.1** Failure (after a 30-day trial) to ONE of the following as confirmed by claims history or submission of medical records:

- Hormonal therapy (e.g., estradiol, Premarin, Prempro)
- Non-hormonal therapy [e.g., clonidine, gabapentin, selective serotonin inhibitors (e.g., paroxetine), serotonin and norepinephrine reuptake inhibitors (e.g., venlafaxine)]

**OR**

**2.2** History of contraindication or intolerance to BOTH of the following (please specify contraindication or intolerance):

- Hormonal therapy (e.g., estradiol, Premarin, Prempro)
- Non-hormonal therapy [e.g., clonidine, gabapentin, selective serotonin inhibitors (e.g., paroxetine), serotonin and norepinephrine reuptake inhibitors (e.g., venlafaxine)]

**AND**

**3** - Patient has received baseline hepatic laboratory tests to rule out the presence of underlying liver disease

|                      |                     |
|----------------------|---------------------|
| Product Name: Veozah |                     |
| Approval Length      | 12 month(s)         |
| Therapy Stage        | Reauthorization     |
| Guideline Type       | Prior Authorization |
| Approval Criteria    |                     |

**1** - Documentation of positive clinical response to therapy (e.g., decrease in frequency and severity of vasomotor symptoms from baseline)

**AND**

**2** - Patient has received periodic evaluation of hepatic laboratory tests to rule out liver injury associated with Veozah use

## **2 . Revision History**

| Date      | Notes                                       |
|-----------|---------------------------------------------|
| 1/14/2025 | Added criteria for hepatic laboratory tests |

Verkazia



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-127288                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Guideline Name</b> | Verkazia                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 8/1/2023 |
|-----------------|----------|

## 1 . Criteria

|                                                |                       |
|------------------------------------------------|-----------------------|
| Product Name:Verkazia, Cyclosporine in Klarity |                       |
| Approval Length                                | 12 month(s)           |
| Therapy Stage                                  | Initial Authorization |
| Guideline Type                                 | Prior Authorization   |
|                                                |                       |

### Approval Criteria

1 - Diagnosis of moderate to severe vernal keratoconjunctivitis

**AND**

2 - ONE of the following:

**2.1** Failure to TWO of the following categories as confirmed by claims history or submission of medical records:

- Ophthalmic antihistamines (e.g., azelastine, olopatadine)
- Ophthalmic mast cell stabilizers (e.g., cromolyn sodium)
- Ophthalmic corticosteroids (e.g., dexamethasone, prednisolone, fluorometholone)

**OR**

**2.2** History of intolerance or contraindication to ALL of the following categories (please specify intolerance or contraindication):

- Ophthalmic antihistamines (e.g., azelastine, olopatadine)
- Ophthalmic mast cell stabilizers (e.g., cromolyn sodium)
- Ophthalmic corticosteroids (e.g., dexamethasone, prednisolone, fluorometholone)

|                                                                             |                     |
|-----------------------------------------------------------------------------|---------------------|
| Product Name: Verkazia, Cyclosporine in Klarity                             |                     |
| Approval Length                                                             | 12 month(s)         |
| Therapy Stage                                                               | Reauthorization     |
| Guideline Type                                                              | Prior Authorization |
| <b>Approval Criteria</b><br>1 - Documentation of positive clinical response |                     |

## 2 . Revision History

UnitedHealthcare Community Plan of New Jersey – Clinical Pharmacy Guidelines

| Date      | Notes                                     |
|-----------|-------------------------------------------|
| 6/29/2023 | Updated formularies, cleaned up criteria. |

Verquvo



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-274203                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Guideline Name</b> | Verquvo                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Arizona (ACUAZ, ACUAZEC)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 7/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                      |                       |
|----------------------|-----------------------|
| Product Name:Verquvo |                       |
| Approval Length      | 12 month(s)           |
| Therapy Stage        | Initial Authorization |
| Guideline Type       | Prior Authorization   |



**Approval Criteria**

**1** - Diagnosis of heart failure

**AND**

**2** - Ejection fraction is less than 45 percent

**AND**

**3** - Heart failure is classified as ONE of the following:

- New York Heart Association Class II
- New York Heart Association Class III
- New York Heart Association Class IV

**AND**

**4** - ONE of the following:

**4.1** Hospitalization for heart failure within the past six months

**OR**

**4.2** Outpatient IV (intravenous) diuretics for heart failure within the past three months

**AND**

**5** - ONE of the following:

**5.1** Patient is on a stabilized dose and receiving concomitant therapy with a maximally tolerated beta-blocker (e.g., bisoprolol, carvedilol, metoprolol) confirmed by claims history or submission of medical records

**OR**

**5.2** Patient has a contraindication or intolerance to beta-blocker therapy (please specify intolerance or contraindication)

**AND**

**6** - ONE of the following:

**6.1** Patient is on a stabilized dose and receiving concomitant therapy with ONE of the following, confirmed by claims history or submission of medical records:

- Angiotensin converting enzyme (ACE) inhibitor (e.g., captopril, enalapril)
- Angiotensin II receptor blocker (ARB) (e.g., losartan)
- Angiotensin receptor-neprilysin inhibitor (ARNI) (e.g., Entresto)

**OR**

**6.2** Patient has an allergy, contraindication, or intolerance to ACE inhibitors, ARBs, and ARNIs (please specify intolerance or contraindication)

**AND**

**7** - ONE of the following:

**7.1** Patient is on a stabilized dose and receiving concomitant therapy with a maximally tolerated aldosterone antagonist (e.g., spironolactone) confirmed by claims history or submission of medical records

**OR**

**7.2** Patient has a contraindication or intolerance to aldosterone antagonist therapy (please specify intolerance or contraindication)

**AND**

**8 - ONE of the following:**

**8.1** Patient is on a stabilized dose and receiving concomitant therapy with a sodium-glucose cotransporter 2 (SGLT2) inhibitor indicated for heart failure (e.g., Farxiga) confirmed by claims history or submission of medical records

**OR**

**8.2** Patient has a contraindication or intolerance to SGLT2 inhibitor therapy (please specify intolerance or contraindication)

**AND**

**9 - Verquvo is prescribed by or in consultation with a cardiologist**

|                                                                                                   |                     |
|---------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Verquvo                                                                              |                     |
| Approval Length                                                                                   | 12 month(s)         |
| Therapy Stage                                                                                     | Reauthorization     |
| Guideline Type                                                                                    | Prior Authorization |
| <b>Approval Criteria</b><br><br><b>1 - Documentation of positive clinical response to therapy</b> |                     |

## 2 . Revision History

| Date      | Notes                                                                          |
|-----------|--------------------------------------------------------------------------------|
| 5/20/2025 | Combined formularies. No changes to clinical criteria. Minor cosmetic updates. |

Verzenio



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-373191                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Guideline Name</b> | Verzenio                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 9/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                       |                       |
|-----------------------|-----------------------|
| Product Name:Verzenio |                       |
| Diagnosis             | Breast Cancer         |
| Approval Length       | 12 month(s)           |
| Therapy Stage         | Initial Authorization |

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Prior Authorization |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of breast cancer</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Disease is hormone-receptor (HR)-positive</p> <p style="text-align: center;"><b>AND</b></p> <p>3 - Disease is human epidermal growth factor receptor 2 (HER2)-negative</p> <p style="text-align: center;"><b>AND</b></p> <p>4 - ONE of the following:</p> <p>4.1 BOTH of the following:</p> <p>4.1.1 Disease is advanced, recurrent, or metastatic</p> <p style="text-align: center;"><b>AND</b></p> <p>4.1.2 ONE of the following:</p> <p>4.1.2.1 Used in combination with an aromatase inhibitor (e.g., anastrozole, letrozole, exemestane) or Faslodex (fulvestrant)</p> <p style="text-align: center;"><b>OR</b></p> <p>4.1.2.2 ALL of the following:</p> <ul style="list-style-type: none"> <li>• Used as monotherapy</li> <li>• Patient has disease progression following endocrine therapy</li> </ul> |                     |

- Patient has already received at least one prior chemotherapy regimen

**OR**

**4.2 ALL of the following:**

**4.2.1** Disease is early breast cancer at high risk of recurrence defined by ONE of the following (confirmed preoperatively and/or at surgery):

**4.2.1.1** Greater than or equal to 4 positive lymph nodes

**OR**

**4.2.1.2 BOTH of the following:**

- 1-3 positive lymph nodes
- Grade 3 disease or tumor size at least 5 cm

**AND**

**4.2.2** Used in combination with an aromatase inhibitor (e.g., anastrozole, letrozole, exemestane) or tamoxifen

**AND**

**4.2.3** Use has not exceeded two years in duration

|                       |                     |
|-----------------------|---------------------|
| Product Name:Verzenio |                     |
| Diagnosis             | Breast Cancer       |
| Approval Length       | 12 month(s)         |
| Therapy Stage         | Reauthorization     |
| Guideline Type        | Prior Authorization |
| Approval Criteria     |                     |

**1 - BOTH of the following:**

- Diagnosis of advanced, recurrent or metastatic breast cancer
- Patient does not show evidence of progressive disease while on Verzenio therapy

**OR**

**2 - ALL of the following:**

- Diagnosis of early breast cancer at high risk of recurrence
- Patient does not show evidence of progressive disease while on Verzenio therapy
- Use has not exceeded two years in duration

|                                                                                                                                                                                                                                                               |                       |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Verzenio                                                                                                                                                                                                                                         |                       |
| Diagnosis                                                                                                                                                                                                                                                     | Endometrial Carcinoma |
| Approval Length                                                                                                                                                                                                                                               | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                 | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1 - Diagnosis of recurrent or metastatic endometrial cancer</b></p> <p><b>AND</b></p> <p><b>2 - Tumor is estrogen receptor (ER)-positive</b></p> <p><b>AND</b></p> <p><b>3 - Used in combination with letrozole</b></p> |                       |

|                       |
|-----------------------|
| Product Name:Verzenio |
|-----------------------|

|                                                                                                                        |                       |
|------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Diagnosis                                                                                                              | Endometrial Carcinoma |
| Approval Length                                                                                                        | 12 month(s)           |
| Therapy Stage                                                                                                          | Reauthorization       |
| Guideline Type                                                                                                         | Prior Authorization   |
| <b>Approval Criteria</b><br><b>1</b> - Patient does not show evidence of progressive disease while on Verzenio therapy |                       |

|                                                                                                                                                                        |                           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Verzenio                                                                                                                                                  |                           |
| Diagnosis                                                                                                                                                              | NCCN Recommended Regimens |
| Approval Length                                                                                                                                                        | 12 month(s)               |
| Therapy Stage                                                                                                                                                          | Initial Authorization     |
| Guideline Type                                                                                                                                                         | Prior Authorization       |
| <b>Approval Criteria</b><br><b>1</b> - Verzenio will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium |                           |

|                                                                                                        |                           |
|--------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Verzenio                                                                                  |                           |
| Diagnosis                                                                                              | NCCN Recommended Regimens |
| Approval Length                                                                                        | 12 month(s)               |
| Therapy Stage                                                                                          | Reauthorization           |
| Guideline Type                                                                                         | Prior Authorization       |
| <b>Approval Criteria</b><br><b>1</b> - Documentation of positive clinical response to Verzenio therapy |                           |

## 2 . Revision History



| Date      | Notes                         |
|-----------|-------------------------------|
| 8/19/2025 | Updated formularies to add IN |

Vioice



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-356189                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Guideline Name</b> | Vioice                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Pennsylvania (ACUPA)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 9/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                                               |                       |
|-----------------------------------------------|-----------------------|
| Product Name: Vioice tablets, Vioice granules |                       |
| Approval Length                               | 12 month(s)           |
| Therapy Stage                                 | Initial Authorization |

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Prior Authorization |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1 - Diagnosis of PIK3CA-Related Overgrowth Spectrum (PROS)</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>2 - ONE of the following:</b></p> <p><b>2.1</b> Confirmed presence of a mutation in the PIK3CA gene</p> <p style="text-align: center;"><b>OR</b></p> <p><b>2.2</b> ONE of the following:</p> <p><b>2.2.1</b> TWO or more of the following spectrum features:</p> <ul style="list-style-type: none"> <li>• Overgrowth: adipose, muscle, nerve, skeletal</li> <li>• Vascular malformations: capillary, venous, arteriovenous, lymphatic</li> <li>• Epidermal nevus</li> </ul> <p style="text-align: center;"><b>OR</b></p> <p><b>2.2.2</b> ONE or more of the following isolated features:</p> <ul style="list-style-type: none"> <li>• Large isolated lymphatic malformation</li> <li>• Isolated macrodactyly or overgrown splayed feet/ hands with overgrown limbs</li> <li>• Truncal adipose overgrowth</li> <li>• Hemimegalencephaly (bilateral) / dysplastic megalencephaly / focal cortical dysplasia</li> <li>• Epidermal nevus</li> <li>• Seborrheic keratoses</li> <li>• Benign lichenoid keratoses</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>3 - Patient is 2 years of age or older</b></p> |                     |

**AND**

**4** - Patient has severe manifestations of PROS requiring systemic therapy

**AND**

**5** - Prescribed by, or in consultation with, a clinical geneticist or a practitioner who has specialized expertise in the management of PROS manifestations

|                                                                                                                                                                                                                                                                                                                                                 |                     |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Vioice tablets, Vioice granules                                                                                                                                                                                                                                                                                                    |                     |
| Approval Length                                                                                                                                                                                                                                                                                                                                 | 12 month(s)         |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                   | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                  | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of positive clinical response to Vioice therapy</p> <p><b>AND</b></p> <p><b>2</b> - Prescribed by, or in consultation with, a clinical geneticist or a practitioner who has specialized expertise in the management of PIK3CA-Related Overgrowth Spectrum (PROS) manifestations</p> |                     |

## 2 . Revision History

| Date      | Notes                                                  |
|-----------|--------------------------------------------------------|
| 7/31/2025 | Combined formularies. No changes to clinical criteria. |

Vitrakvi



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-208221                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Guideline Name</b> | Vitrakvi                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 4/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                       |                       |
|-----------------------|-----------------------|
| Product Name:Vitrakvi |                       |
| Diagnosis             | Solid Tumors          |
| Approval Length       | 12 month(s)           |
| Therapy Stage         | Initial Authorization |

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Prior Authorization |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Presence of a solid tumor</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Disease is positive for neurotrophic receptor tyrosine kinase (NTRK) gene fusion (e.g., ETV6-NTRK3, TPM3-NTRK1, LMNA-NTRK1, etc.)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Disease is without a known acquired resistance mutation (e.g., TRKA G595R, G623R, G696A, F617L)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>4</b> - Disease is ONE of the following:</p> <ul style="list-style-type: none"> <li>• Metastatic</li> <li>• Unresectable</li> </ul> |                     |

|                                                                                                                                   |                     |
|-----------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Vitrakvi                                                                                                             |                     |
| Diagnosis                                                                                                                         | Solid tumors        |
| Approval Length                                                                                                                   | 12 month(s)         |
| Therapy Stage                                                                                                                     | Reauthorization     |
| Guideline Type                                                                                                                    | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Patient does not show evidence of progressive disease while on Vitrakvi therapy</p> |                     |

|                                                                                                                                         |                           |
|-----------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Vitrakvi                                                                                                                   |                           |
| Diagnosis                                                                                                                               | NCCN Recommended Regimens |
| Approval Length                                                                                                                         | 12 month(s)               |
| Therapy Stage                                                                                                                           | Initial Authorization     |
| Guideline Type                                                                                                                          | Prior Authorization       |
| <b>Approval Criteria</b><br><br>1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium |                           |

|                                                                                                     |                           |
|-----------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Vitrakvi                                                                               |                           |
| Diagnosis                                                                                           | NCCN Recommended Regimens |
| Approval Length                                                                                     | 12 month(s)               |
| Therapy Stage                                                                                       | Reauthorization           |
| Guideline Type                                                                                      | Prior Authorization       |
| <b>Approval Criteria</b><br><br>1 - Documentation of positive clinical response to Vitrakvi therapy |                           |

## 2 . Revision History

| Date     | Notes               |
|----------|---------------------|
| 3/6/2025 | Updated formularies |

Vivjoa



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-426243                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Guideline Name</b> | Vivjoa                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 11/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                      |                     |
|----------------------|---------------------|
| Product Name: Vivjoa |                     |
| Approval Length      | 4 month(s)          |
| Guideline Type       | Prior Authorization |
| Approval Criteria    |                     |



**1 - Diagnosis of recurrent vulvovaginal candidiasis**

**AND**

**2 - Patient is not of reproductive potential (i.e., persons who are biological females who are postmenopausal or have another reason for permanent infertility [(e.g., tubal ligation, hysterectomy, salpingo-oophorectomy)])**

**AND**

**3 - BOTH of the following:**

**3.1 Other causes (including but not limited to bacterial vaginosis or trichomoniasis) have been ruled out**

**AND**

**3.2 Failure of a maintenance course of oral fluconazole defined as 100-mg, 150-mg, or 200-mg taken weekly for 6 months confirmed by claims history or submission of medical records.**

**AND**

**4 - Prescribed by, or in consultation with, ONE of the following:**

- Infectious disease physician
- Obstetrician/Gynecologist

## 2 . Revision History

| Date       | Notes                                                                          |
|------------|--------------------------------------------------------------------------------|
| 10/20/2025 | Combined formularies. Minor cosmetic updates. No changes to clinical criteria. |

Vizimpro



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-118462                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Guideline Name</b> | Vizimpro                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 2/1/2023 |
|-----------------|----------|

## 1 . Criteria

|                       |                                    |
|-----------------------|------------------------------------|
| Product Name:Vizimpro |                                    |
| Diagnosis             | Non-Small Cell Lung Cancer (NSCLC) |
| Approval Length       | 12 month(s)                        |
| Therapy Stage         | Initial Authorization              |
| Guideline Type        | Prior Authorization                |

**Approval Criteria**

**1** - Diagnosis of non-small cell lung cancer (NSCLC)

**AND**

**2** - Disease is recurrent, advanced, or metastatic

**AND**

**3** - Disease is positive for ONE of the following EGFR (epidermal growth factor receptor) mutations:

- Exon 19 deletion
- Exon 21 L858R substitution
- S768I
- L861Q
- G719X

|                                                                                                                                   |                                    |
|-----------------------------------------------------------------------------------------------------------------------------------|------------------------------------|
| Product Name:Vizimpro                                                                                                             |                                    |
| Diagnosis                                                                                                                         | Non-Small Cell Lung Cancer (NSCLC) |
| Approval Length                                                                                                                   | 12 month(s)                        |
| Therapy Stage                                                                                                                     | Reauthorization                    |
| Guideline Type                                                                                                                    | Prior Authorization                |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Patient does not show evidence of progressive disease while on Vizimpro therapy</p> |                                    |

|                       |                           |
|-----------------------|---------------------------|
| Product Name:Vizimpro |                           |
| Diagnosis             | NCCN Recommended Regimens |
| Approval Length       | 12 month(s)               |

|                                                                                                                                                |                       |
|------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                                                                                  | Initial Authorization |
| Guideline Type                                                                                                                                 | Prior Authorization   |
| <b>Approval Criteria</b><br><br><b>1</b> - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium |                       |

|                                                                                                            |                           |
|------------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Vizimpro                                                                                      |                           |
| Diagnosis                                                                                                  | NCCN Recommended Regimens |
| Approval Length                                                                                            | 12 month(s)               |
| Therapy Stage                                                                                              | Reauthorization           |
| Guideline Type                                                                                             | Prior Authorization       |
| <b>Approval Criteria</b><br><br><b>1</b> - Documentation of positive clinical response to Vizimpro therapy |                           |

## 2 . Revision History

| Date       | Notes                                                                        |
|------------|------------------------------------------------------------------------------|
| 12/16/2022 | Updated criteria to add EGFR mutations, cleaned up indications and criteria. |

Vonjo



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-398295                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Guideline Name</b> | Vonjo                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Washington (ACUWA, ACUWAAHE, ACUWAC)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 10/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                     |                                    |
|---------------------|------------------------------------|
| Product Name: Vonjo |                                    |
| Diagnosis           | Myeloproliferative Neoplasms (MPN) |
| Approval Length     | 12 month(s)                        |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                       |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1 - Both of the following:</b></p> <p><b>1.1 One of the following diagnosis:</b></p> <ul style="list-style-type: none"> <li>• Primary myelofibrosis</li> <li>• Post-polycythemia vera myelofibrosis</li> <li>• Post-essential thrombocythemia myelofibrosis</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>1.2 One of the following:</b></p> <p><b>1.2.1 Both of the following:</b></p> <ul style="list-style-type: none"> <li>• Patient has symptomatic lower-risk myelofibrosis</li> <li>• Patient has a platelet count less than 50 x 109/L</li> </ul> <p style="text-align: center;"><b>OR</b></p> <p><b>1.2.2 Both of the following:</b></p> <ul style="list-style-type: none"> <li>• Patient has higher-risk myelofibrosis</li> <li>• Patient has a platelet count less than 50 x 109/L</li> </ul> <p style="text-align: center;"><b>OR</b></p> <p><b>1.2.3 All of the following:</b></p> <ul style="list-style-type: none"> <li>• Patient has higher-risk myelofibrosis</li> <li>• Patient has symptomatic splenomegaly and/or constitutional symptoms</li> <li>• Patient has a platelet count of at least 50 x 109/L</li> </ul> |                       |

**OR**

**2** - Used for treatment of myelofibrosis-associated anemia

**OR**

**3** - Both of the following:

**3.1** Diagnosis of accelerated/blast phase myeloproliferative neoplasm

**AND**

**3.2** One of the following:

**3.2.1** Continued treatment near the start of conditioning therapy in transplant candidates for the improvement of splenomegaly and other disease-related symptoms

**OR**

**3.2.2** Palliation in combination with hypomethylating agents (azacitidine or decitabine) as bridging therapy prior to transplant

**OR**

**3.2.3** Palliation in combination with hypomethylating agents (azacitidine or decitabine) if not a candidate for transplant

| Product Name: Vonjo |                                    |
|---------------------|------------------------------------|
| Diagnosis           | Myeloproliferative Neoplasms (MPN) |
| Approval Length     | 12 month(s)                        |
| Therapy Stage       | Reauthorization                    |
| Guideline Type      | Prior Authorization                |
|                     |                                    |

**Approval Criteria**

1 - Documentation that patient has evidence of symptom improvement or reduction in spleen volume while on Vonjo

Product Name: Vonjo

|           |                           |
|-----------|---------------------------|
| Diagnosis | NCCN Recommended Regimens |
|-----------|---------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

1 - Vonjo will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name: Vonjo

|           |                           |
|-----------|---------------------------|
| Diagnosis | NCCN Recommended Regimens |
|-----------|---------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                 |
|---------------|-----------------|
| Therapy Stage | Reauthorization |
|---------------|-----------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

1 - Documentation of positive clinical response to Vonjo therapy

## 2 . Revision History

| Date      | Notes                                                                            |
|-----------|----------------------------------------------------------------------------------|
| 9/19/2025 | Combined formularies. Changed dx from MF to MPN. Criteria updates for dx of MPN. |



Voranigo



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-164769                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Guideline Name</b> | Voranigo                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>• Medicaid - Community &amp; State Washington (ACUWA, ACUWAAHE, ACUWAC)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 3/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                        |                               |
|------------------------|-------------------------------|
| Product Name: Voranigo |                               |
| Diagnosis              | Astrocytoma/Oligodendroglioma |
| Approval Length        | 12 month(s)                   |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                       |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - One of the following diagnoses:</p> <ul style="list-style-type: none"> <li>• Astrocytoma</li> <li>• Oligodendroglioma</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Presence of IDH1 or IDH2 mutation</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - History of one of the following:</p> <ul style="list-style-type: none"> <li>• Biopsy</li> <li>• Sub-total resection</li> <li>• Gross total resection</li> </ul> |                       |

|                                                                                                                                  |                               |
|----------------------------------------------------------------------------------------------------------------------------------|-------------------------------|
| Product Name:Vorango                                                                                                             |                               |
| Diagnosis                                                                                                                        | Astrocytoma/Oligodendroglioma |
| Approval Length                                                                                                                  | 12 month(s)                   |
| Therapy Stage                                                                                                                    | Reauthorization               |
| Guideline Type                                                                                                                   | Prior Authorization           |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Patient does not show evidence of progressive disease while on Vorango therapy</p> |                               |

|                      |
|----------------------|
| Product Name:Vorango |
|----------------------|

|                                                                                                                                                |                           |
|------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Diagnosis                                                                                                                                      | NCCN Recommended Regimens |
| Approval Length                                                                                                                                | 12 month(s)               |
| Therapy Stage                                                                                                                                  | Initial Authorization     |
| Guideline Type                                                                                                                                 | Prior Authorization       |
| <b>Approval Criteria</b><br><br><b>1</b> - Use is supported by the National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium |                           |

|                                                                                                            |                           |
|------------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:VoraniGo                                                                                      |                           |
| Diagnosis                                                                                                  | NCCN Recommended Regimens |
| Approval Length                                                                                            | 12 month(s)               |
| Therapy Stage                                                                                              | Reauthorization           |
| Guideline Type                                                                                             | Prior Authorization       |
| <b>Approval Criteria</b><br><br><b>1</b> - Documentation of positive clinical response to Voranigo therapy |                           |

## 2 . Revision History

| Date     | Notes                                                    |
|----------|----------------------------------------------------------|
| 2/5/2025 | Updated formularies. Removed Grade 2 disease requirement |

Votrient



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-163948                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Guideline Name</b> | Votrient                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 2/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                                                 |                                          |
|-------------------------------------------------|------------------------------------------|
| Product Name: Brand Votrient, generic pazopanib |                                          |
| Diagnosis                                       | Renal Cell Carcinoma (RCC)/Kidney Cancer |
| Approval Length                                 | 12 month(s)                              |
| Therapy Stage                                   | Initial Authorization                    |
| Guideline Type                                  | Prior Authorization                      |

### Approval Criteria

1 - BOTH of the following

1.1 Diagnosis of renal cell carcinoma (RCC)

**AND**

1.2 ONE of the following:

- Disease has relapsed
- Stage IV disease
- Disease is advanced

**OR**

2 - Diagnosis of von Hippel-Lindau (VHL)-associated renal cell carcinoma

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name: Brand Votrient, generic pazopanib                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                           |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Soft Tissue Sarcoma (STS) |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 12 month(s)               |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Initial Authorization     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Prior Authorization       |
| <b>Approval Criteria</b><br><p>1 - Patient has ONE of the following diagnoses:</p> <ul style="list-style-type: none"> <li>• Angiosarcoma</li> <li>• Alveolar soft part sarcoma</li> <li>• Pleomorphic rhabdomyosarcoma</li> <li>• Retroperitoneal/intra-abdominal disease that is unresectable, stage IV, or postoperative treatment for residual disease</li> <li>• Soft tissue sarcoma of the extremity/superficial trunk or head/neck with disease that is stage IV or recurrent and has disseminated metastases</li> <li>• Solitary fibrous tumor/hemangiopericytoma</li> </ul> |                           |

- Desmoid tumors (aggressive fibromatosis)
- Dermatofibrosarcoma Protuberans (DFSP) with Fibrosarcomatous Transformation
- Dedifferentiated Chordoma
- Epithelioid hemangioendothelioma
- Extraskkeletal myxoid chondrosarcoma

|                                                 |                       |
|-------------------------------------------------|-----------------------|
| Product Name: Brand Votrient, generic pazopanib |                       |
| Diagnosis                                       | Thyroid Carcinoma     |
| Approval Length                                 | 12 month(s)           |
| Therapy Stage                                   | Initial Authorization |
| Guideline Type                                  | Prior Authorization   |

**Approval Criteria**

1 - All of the following:

1.1 Diagnosis of one of the following:

- Follicular carcinoma
- Oncocytic carcinoma
- Papillary carcinoma

**AND**

1.2 One of the following:

- Unresectable locoregional recurrent disease
- Persistent disease
- Metastatic disease

**AND**

1.3 One of the following:

- Patient has symptomatic disease
- Patient has progressive disease

**AND**

**1.4** One of the following:

- Disease is refractory to radioactive iodine treatment
- Distant metastatic disease not amenable to radioactive iodine treatment

**OR**

**2** - All of the following:

**2.1** Diagnosis of medullary carcinoma

**AND**

**2.2** One of the following:

- Disease is progressive
- Disease is symptomatic with distant metastases

**AND**

**2.3** One of the following:

**2.3.1** Failure to ONE of the following, as confirmed by claims history or submission of medical records:

- Caprelsa (vandetanib)
- Cometriq (cabozantinib)

**OR**

**2.3.2** History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- Caprelsa (vandetanib)
- Cometriq (cabozantinib)

|                                                                                                                                                                                                                                                                                                            |                       |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Brand Votrient, generic pazopanib                                                                                                                                                                                                                                                             |                       |
| Diagnosis                                                                                                                                                                                                                                                                                                  | Uterine Sarcoma       |
| Approval Length                                                                                                                                                                                                                                                                                            | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                              | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                             | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of uterine sarcoma</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - One of the following:</p> <ul style="list-style-type: none"> <li>• Disease is advanced</li> <li>• Disease is recurrent/metastatic</li> <li>• Disease is inoperable</li> </ul> |                       |

|                                                                                                                                                                                                                                                                                 |                       |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Brand Votrient, generic pazopanib                                                                                                                                                                                                                                  |                       |
| Diagnosis                                                                                                                                                                                                                                                                       | Ovarian Cancer        |
| Approval Length                                                                                                                                                                                                                                                                 | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                   | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                  | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of ONE of the following:</p> <ul style="list-style-type: none"> <li>• Epithelial ovarian cancer</li> <li>• Fallopian tube cancer</li> <li>• Primary peritoneal cancer</li> </ul> <p style="text-align: center;"><b>AND</b></p> |                       |



**2** - ONE of the following:

- Disease is persistent
- Disease is recurrent

|                                                                                                                                                                      |                       |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Brand Votrient, generic pazopanib                                                                                                                       |                       |
| Diagnosis                                                                                                                                                            | Chondrosarcoma        |
| Approval Length                                                                                                                                                      | 12 month(s)           |
| Therapy Stage                                                                                                                                                        | Initial Authorization |
| Guideline Type                                                                                                                                                       | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of chondrosarcoma</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Disease is metastatic and widespread</p> |                       |

|                                                                                                                                              |                                        |
|----------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------|
| Product Name:Brand Votrient, generic pazopanib                                                                                               |                                        |
| Diagnosis                                                                                                                                    | Gastrointestinal Stromal Tumors (GIST) |
| Approval Length                                                                                                                              | 12 month(s)                            |
| Therapy Stage                                                                                                                                | Initial Authorization                  |
| Guideline Type                                                                                                                               | Prior Authorization                    |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of Gastrointestinal Stromal Tumors (GIST)</p> <p style="text-align: center;"><b>AND</b></p> |                                        |

**2** - Disease is unresectable, progressive, or metastatic

**AND**

**3** - One of the following:

**3.1** Used as first-line therapy in SDH-deficient GIST

**OR**

**3.2** Used after progression on ALL of the following:

- Imatinib (generic Gleevac)
- Sunitinib (generic Sutent)
- Stivarga (regorafenib)
- Standard dose Qinlock (ripretinib)

|                                                                                                                                                                       |                       |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Brand Votrient, generic pazopanib                                                                                                                        |                       |
| Diagnosis                                                                                                                                                             | Merkel Cell Carcinoma |
| Approval Length                                                                                                                                                       | 12 month(s)           |
| Therapy Stage                                                                                                                                                         | Initial Authorization |
| Guideline Type                                                                                                                                                        | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of Merkel Cell Carcinoma</p> <p><b>AND</b></p> <p><b>2</b> - Disease is M1 disseminated</p> <p><b>AND</b></p> |                       |

**3** - One of the following:

**3.1** Anti-PD-L1 or anti-PD-1 therapy is contraindicated

**OR**

**3.2** Disease has progressed on anti-PD-L1 or anti-PD-1 therapy

| Product Name:Brand Votrient, generic pazopanib                                                                             |                                                                                                                                                                                                        |
|----------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Diagnosis                                                                                                                  | Renal Cell Carcinoma (RCC)/Kidney Cancer, Soft Tissue Sarcoma (STS), Thyroid Carcinoma, Uterine Sarcoma, Ovarian Cancer, Chondrosarcoma, Gastrointestinal Stromal Tumors (GIST), Merkel Cell Carcinoma |
| Approval Length                                                                                                            | 12 month(s)                                                                                                                                                                                            |
| Therapy Stage                                                                                                              | Reauthorization                                                                                                                                                                                        |
| Guideline Type                                                                                                             | Prior Authorization                                                                                                                                                                                    |
| <b>Approval Criteria</b><br><br><b>1</b> - Patient does not show evidence of progressive disease while on Votrient therapy |                                                                                                                                                                                                        |

| Product Name:Brand Votrient, generic pazopanib                                                                                                                             |                           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Diagnosis                                                                                                                                                                  | NCCN Recommended Regimens |
| Approval Length                                                                                                                                                            | 12 month(s)               |
| Therapy Stage                                                                                                                                                              | Initial Authorization     |
| Guideline Type                                                                                                                                                             | Prior Authorization       |
| <b>Approval Criteria</b><br><br><b>1</b> - Votrient will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium |                           |

|                                                                                                     |                           |
|-----------------------------------------------------------------------------------------------------|---------------------------|
| Product Name: Brand Votrient, generic pazopanib                                                     |                           |
| Diagnosis                                                                                           | NCCN Recommended Regimens |
| Approval Length                                                                                     | 12 month(s)               |
| Therapy Stage                                                                                       | Reauthorization           |
| Guideline Type                                                                                      | Prior Authorization       |
| <b>Approval Criteria</b><br><br>1 - Documentation of positive clinical response to Votrient therapy |                           |

## 2 . Revision History

| Date      | Notes                        |
|-----------|------------------------------|
| 1/16/2025 | Updated criteria for Sarcoma |

Vowst



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-164987                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Guideline Name</b> | Vowst                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State Michigan (ACUMI)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania (ACUPA)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 3/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                    |                     |
|--------------------|---------------------|
| Product Name:Vowst |                     |
| Approval Length    | 1 month(s)          |
| Guideline Type     | Prior Authorization |

### **Approval Criteria**

**1** - Diagnosis of recurrent *Clostridioides difficile* infection (rCDI) as defined by BOTH of the following:

**1.1** Presence of diarrhea defined as a passage of 3 or more loose bowel movements within a 24-hour period for 2 consecutive days

**AND**

**1.2** A positive stool test for *Clostridioides difficile* toxin

**AND**

**2** - Patient is 18 years of age or older

**AND**

**3** - Patient has had one or more recurrences of CDI following an initial episode of CDI

**AND**

**4** - Patient has completed at least 10 days of ONE of the following antibiotic therapies for rCDI 2 to 4 days prior to initiating Vowst as confirmed by claims history or submission of medical records:

- Oral vancomycin
- Difidol (fidaxomicin)

**AND**

**5** - Previous episode of CDI is under control [e.g., less than 3 unformed/loose (i.e., Bristol Stool Scale type 6-7) stools/day for 2 consecutive days]

**AND**

**6** - Patient will drink magnesium citrate on the day before and at least 8 hours prior to taking the first dose of Vowst

**AND**

**7** - Prescribed by or in consultation with one of the following:

- Gastroenterologist
- Infectious disease specialist

## 2 . Revision History

| Date      | Notes                                                 |
|-----------|-------------------------------------------------------|
| 2/11/2025 | Updated formularies. No changes to clinical criteria. |

Voxzogo



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-210193                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Guideline Name</b> | Voxzogo                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania (ACUPA)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> </ul> |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 3/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                      |                       |
|----------------------|-----------------------|
| Product Name:Voxzogo |                       |
| Approval Length      | 12 month(s)           |
| Therapy Stage        | Initial Authorization |



| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Prior Authorization |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Patient is less than 18 years of age</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Diagnosis of achondroplasia as confirmed by ONE of the following:</p> <p><b>2.1</b> Submission of medical records documenting BOTH of the following:</p> <p><b>2.1.1</b> Patient has clinical manifestations characteristic of achondroplasia (e.g., macrocephaly, frontal bossing, midface retrusion, disproportionate short stature with rhizomelic shortening of the arms and the legs, brachydactyly, trident configuration of the hands, thoracolumbar kyphosis, and accentuated lumbar lordosis)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2.1.2</b> Patient has radiographic findings characteristic of achondroplasia (e.g., large calvaria and narrowing of the foramen magnum region, undertubulated, shortened long bones with metaphyseal abnormalities, narrowing of the interpedicular distance of the caudal spine, square ilia and horizontal acetabula, small sacrosciatic notches, proximal scooping of the femoral metaphyses, and short and narrow chest)</p> <p style="text-align: center;"><b>OR</b></p> <p><b>2.2</b> Submission of medical records documenting molecular genetic testing confirmed c.1138G &gt; A or c.1138G &gt; C variant (i.e., p.Gly380Arg mutation) in the fibroblast growth factor receptor-3 (FGFR3) gene</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Patient has open epiphyses</p> <p style="text-align: center;"><b>AND</b></p> |                     |

**4 - BOTH of the following:**

**4.1** Patient has not had limb-lengthening surgery in the previous 18 months

**AND**

**4.2** Patient does not plan to have limb-lengthening surgery while on Voxzogo

**AND**

**5 - Prescribed by ONE of the following:**

- Clinical geneticist
- Endocrinologist
- A practitioner who has specialized expertise in the management of achondroplasia

|                                                                                                                                                                                                                                                                                                                                                                          |                     |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Voxzogo                                                                                                                                                                                                                                                                                                                                                     |                     |
| Approval Length                                                                                                                                                                                                                                                                                                                                                          | 12 month(s)         |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                            | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                           | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1 -</b> Documentation of positive clinical response to Voxzogo therapy [e.g., improvement in annualized growth velocity (AGV) compared to baseline]</p> <p><b>AND</b></p> <p><b>2 -</b> Patient has open epiphyses</p> <p><b>AND</b></p> <p><b>3 -</b> Patient does not plan to have limb-lengthening surgery while on Voxzogo</p> |                     |

**AND**

**4** - Prescribed by or in consultation with ONE of the following:

- Clinical geneticist
- Endocrinologist
- A practitioner who has specialized expertise in the management of achondroplasia

## **2 . Revision History**

| Date     | Notes                                                 |
|----------|-------------------------------------------------------|
| 3/6/2025 | Added PA-CAID for 4/1 go-live. No change to criteria. |

Voydeya



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-373192                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Guideline Name</b> | Voydeya                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Formulary</b>      | Medicaid - Community & State Colorado (ACUCO, ACUCOC)<br>Medicaid - Community & State Hawaii (ACUHI, ACUHIEC)<br>Medicaid - Community & State Maryland (ACUMD)<br>Medicaid - Community & State New Jersey (PSI2300)<br>Medicaid - Community & State New York (ACUNY, ACUNYM)<br>Medicaid - Community & State New York EPP (ACUNYEPP)<br>Medicaid - Community & State Pennsylvania CHIP (ACUPAC)<br>Medicaid - Community & State Rhode Island (ACURI)<br>Medicaid - Community & State Virginia (ACUVA, ACUVAC, ACUVAEC)<br>Medicaid - Community & State Pennsylvania (ACUPA)<br>Medicaid - Community & State Nebraska (ACUNE)<br>Medicaid - Community & State Indiana (ACUIN)<br>Medicaid - Community & State New Mexico (ACUNM) |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 9/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                      |                       |
|----------------------|-----------------------|
| Product Name:Voydeya |                       |
| Approval Length      | 12 month(s)           |
| Therapy Stage        | Initial Authorization |

| Guideline Type | Prior Authorization                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                | <p><b>Approval Criteria</b></p> <p><b>1</b> - Submission of medical records (e.g., chart notes, laboratory values, etc.) documenting the diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) as confirmed by both of the following:</p> <p>Flow cytometry analysis confirming presence of PNH clones</p> <p>Laboratory results, signs, and/or symptoms attributed to PNH (e.g., abdominal pain, anemia, dyspnea, extreme fatigue, smooth muscle dystonia, unexplained/unusual thrombosis, hemolysis/hemoglobinuria, kidney disease, pulmonary hypertension, etc.)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - All of the following:</p> <p>Patient is currently receiving complement protein C5 inhibitor eculizumab or Ultomiris (ravulizumab)</p> <p>Patient is experiencing extravascular hemolysis (EVH) while on complement protein C5 inhibitor eculizumab or Ultomiris (ravulizumab)</p> <p>Patient will continue to receive complement protein C5 inhibitor eculizumab or Ultomiris (ravulizumab)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Patient is not receiving Voydeya in combination with a complement protein C3 inhibitor [e.g., Empaveli (Pegcetacoplan)] or a complement factor B inhibitor [e.g., Fabhalta (iptacopan)] used for the treatment of PNH</p> <p style="text-align: center;"><b>AND</b></p> <p><b>4</b> - Prescribed by, or in consultation with one of the following:</p> <p>Hematologist</p> |

Oncologist

|                      |                     |
|----------------------|---------------------|
| Product Name:Voydeya |                     |
| Approval Length      | 12 month(s)         |
| Therapy Stage        | Reauthorization     |
| Guideline Type       | Prior Authorization |

**Approval Criteria**

**1** - Documentation of positive clinical response to Voydeya therapy [e.g., decrease in extravascular hemolysis (EVH), increased or stabilization of hemoglobin levels, reduction in transfusions, improvement in hemolysis, etc.]]

**AND**

**2** - Patient continues to receive Voydeya in combination with complement protein C5 inhibitor eculizumab or Ultomiris (ravulizumab) for PNH

**AND**

**3** - Patient is not receiving Voydeya in combination with a complement protein C3 inhibitor [e.g., Empaveli (Pegcetacoplan)] or a complement factor B inhibitor [e.g., Fabhalta (iptacopan)] used for the treatment of PNH

**AND**

**4** - Prescribed by, or in consultation with one of the following:

Hematologist

Oncologist

## 2 . Revision History

| Date      | Notes                         |
|-----------|-------------------------------|
| 8/19/2025 | Updated formularies to add IN |

Vtama



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-432344                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Guideline Name</b> | Vtama                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Formulary</b>      | Medicaid - Community & State Colorado (ACUCO, ACUCOC)<br>Medicaid - Community & State Hawaii (ACUHI, ACUHIEC)<br>Medicaid - Community & State Maryland (ACUMD)<br>Medicaid - Community & State New Jersey (PSI2300)<br>Medicaid - Community & State New York (ACUNY, ACUNYM)<br>Medicaid - Community & State New York EPP (ACUNYEPP)<br>Medicaid - Community & State Pennsylvania CHIP (ACUPAC)<br>Medicaid - Community & State Rhode Island (ACURI)<br>Medicaid - Community & State New Mexico (ACUNM) |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 12/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                    |                       |
|--------------------|-----------------------|
| Product Name:Vtama |                       |
| Diagnosis          | Plaque Psoriasis      |
| Approval Length    | 12 month(s)           |
| Therapy Stage      | Initial Authorization |
| Guideline Type     | Prior Authorization   |



## **Approval Criteria**

**1** - Diagnosis of plaque psoriasis

**AND**

**2** - ONE of the following:

**2.1** Failure to a minimum duration of a 4-week trial to TWO of the following topical therapies as confirmed by claims history or submission of medical records:

Corticosteroids (e.g., betamethasone, clobetasol, desonide)

Vitamin D analogs (e.g., calcitriol, calcipotriene)

Tazarotene

Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)

Anthralin

Coal tar

**OR**

**2.2** History of intolerance or contraindication to ALL of the following topical therapies (please specify intolerance or contraindication):

Corticosteroids (e.g., betamethasone, clobetasol, desonide)

Vitamin D analogs (e.g., calcitriol, calcipotriene)

Tazarotene

Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)

Anthralin

Coal tar

**OR**

**2.3** Patient is currently on Vtama therapy as confirmed by claims history or submission of medical records

**AND**

**3** - Patient is NOT receiving Vtama in combination with a targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                     |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Vtama                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                     |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Plaque Psoriasis    |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 12 month(s)         |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of positive clinical response to therapy</p> <p><b>AND</b></p> <p><b>2</b> - Patient is NOT receiving Vtama in combination with a targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]</p> |                     |

|                    |                   |
|--------------------|-------------------|
| Product Name:Vtama |                   |
| Diagnosis          | Atopic Dermatitis |
| Approval Length    | 12 month(s)       |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                       |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1 - Diagnosis of atopic dermatitis</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>2 - ONE of the following:</b></p> <p><b>2.1</b> Failure to TWO of the following therapeutic classes of topical therapies, confirmed by claims history or submission of medical records:</p> <p>One medium, high, or very-high potency topical corticosteroid [e.g., mometasone furoate (generic Elocon), fluocinolone acetonide (generic Synalar), fluocinonide (generic Lidex)]</p> <p>One topical calcineurin inhibitor [e.g., pimecrolimus (generic Elidel), tacrolimus (generic Protopic)]</p> <p>Eucrisa (crisaborole)</p> <p style="text-align: center;"><b>OR</b></p> <p><b>2.2</b> History of intolerance or contraindication to ALL of the following therapeutic classes of topical therapies (please specify intolerance or contraindication):</p> <p>One medium, high, or very-high potency topical corticosteroid [e.g., mometasone furoate (generic Elocon), fluocinolone acetonide (generic Synalar), fluocinonide (generic Lidex)]</p> <p>One topical calcineurin inhibitor [e.g., pimecrolimus (generic Elidel), tacrolimus (generic Protopic)]</p> <p>Eucrisa (crisaborole)</p> <p style="text-align: center;"><b>OR</b></p> |                       |

**2.3** Patient is currently on Vtama therapy as confirmed by claims history or submission of medical records

**AND**

**3** - Patient is NOT receiving Vtama in combination with a targeted immunomodulator [e.g., Adbry (tralokinumab-ldrm), Cibinqo (abrocitinib), Dupixent (dupilumab), Rinvoq (upadacitinib)]

|                                                                                                                                                                                                                                                                                                                                  |                     |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Vtama                                                                                                                                                                                                                                                                                                               |                     |
| Diagnosis                                                                                                                                                                                                                                                                                                                        | Atopic Dermatitis   |
| Approval Length                                                                                                                                                                                                                                                                                                                  | 12 month(s)         |
| Therapy Stage                                                                                                                                                                                                                                                                                                                    | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                                                                                                   | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of positive clinical response to therapy</p> <p><b>AND</b></p> <p><b>2</b> - Patient is NOT receiving Vtama in combination with a targeted immunomodulator [e.g., Adbry (tralokinumab-ldrm), Cibinqo (abrocitinib), Dupixent (dupilumab), Rinvoq (upadacitinib)]</p> |                     |

## 2 . Revision History

| Date      | Notes                                                                                                                            |
|-----------|----------------------------------------------------------------------------------------------------------------------------------|
| 11/4/2025 | Updated atopic dermatitis topical step therapy options to list a medium, high, or very high potency TCS. Removed VA eff 12/1/25. |

Vyalev



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-164784                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Guideline Name</b> | Vyalev                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Formulary</b>      | Medicaid - Community & State Colorado (ACUCO, ACUCOC)<br>Medicaid - Community & State Hawaii (ACUHI, ACUHIEC)<br>Medicaid - Community & State Indiana (ACUIN)<br>Medicaid - Community & State Maryland (ACUMD)<br>Medicaid - Community & State Michigan (ACUMI)<br>Medicaid - Community & State New Jersey (PSI2300)<br>Medicaid - Community & State New Mexico (ACUNM)<br>Medicaid - Community & State New York (ACUNY, ACUNYM)<br>Medicaid - Community & State New York EPP (ACUNYEPP)<br>Medicaid - Community & State Pennsylvania CHIP (ACUPAC)<br>Medicaid - Community & State Rhode Island (ACURI)<br>Medicaid - Community & State Virginia (ACUVA, ACUVAC, ACUVAEC)<br>Medicaid - Community & State Washington (ACUWA, ACUWAAHE, ACUWAC) |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 3/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                     |             |
|---------------------|-------------|
| Product Name:Vyalev |             |
| Approval Length     | 12 month(s) |

|                                                                                                                                                                                                                                                                                                                                                                                       |                       |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                         | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                        | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of advanced Parkinson's disease</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Patient has inadequately controlled motor fluctuations despite being treated with optimized oral therapies (e.g. levodopa)</p> <p style="text-align: center;"><b>AND</b></p> <p>3 - Prescribed by or in consultation with a neurologist</p> |                       |

|                                                                                                                                                                                  |                     |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Vyalev                                                                                                                                                              |                     |
| Approval Length                                                                                                                                                                  | 12 month(s)         |
| Therapy Stage                                                                                                                                                                    | Reauthorization     |
| Guideline Type                                                                                                                                                                   | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p>1 - Documentation of positive clinical response to Vyalev therapy demonstrated by an increase in “on” time without troublesome dyskinesia</p> |                     |

## 2 . Revision History

| Date     | Notes         |
|----------|---------------|
| 2/5/2025 | New guideline |

Vykat XR



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-366187                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Guideline Name</b> | Vykat XR                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Formulary</b>      | Medicaid - Community & State Colorado (ACUCO, ACUCOC)<br>Medicaid - Community & State Maryland (ACUMD)<br>Medicaid - Community & State New Jersey (PSI2300)<br>Medicaid - Community & State New York (ACUNY, ACUNYM)<br>Medicaid - Community & State New York EPP (ACUNYEPP)<br>Medicaid - Community & State Pennsylvania CHIP (ACUPAC)<br>Medicaid - Community & State Rhode Island (ACURI)<br>Medicaid - Community & State Virginia (ACUVA, ACUVAC, ACUVAEC)<br>Medicaid - Community & State Washington (ACUWA, ACUWAAHE, ACUWAC)<br>Medicaid - Community & State New Mexico (ACUNM)<br>Medicaid - Community & State Pennsylvania (ACUPA) |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 9/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                       |                       |
|-----------------------|-----------------------|
| Product Name:Vykat XR |                       |
| Approval Length       | 12 month(s)           |
| Therapy Stage         | Initial Authorization |

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Prior Authorization |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of hyperphagia associated with Prader-Willi Syndrome</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Prader-Willi Syndrome is confirmed by genetic testing</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Patient is at least 4 years of age or older</p> <p style="text-align: center;"><b>AND</b></p> <p><b>4</b> - Prescribed by or in consultation with an endocrinologist, geneticist, or a specialist with knowledge in the treatment of Prader-Willi syndrome</p> |                     |

|                                                                                                                   |                     |
|-------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Vykat XR                                                                                             |                     |
| Approval Length                                                                                                   | 12 month(s)         |
| Therapy Stage                                                                                                     | Reauthorization     |
| Guideline Type                                                                                                    | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of positive clinical response to Vykat XR therapy</p> |                     |

## 2 . Revision History

| Date | Notes |
|------|-------|
|------|-------|



|           |     |
|-----------|-----|
| 8/12/2025 | New |
|-----------|-----|

Vyndaqel and Vyndamax



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-208204                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Guideline Name</b> | Vyndaqel and Vyndamax                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Formulary</b>      | Medicaid - Community & State Colorado (ACUCO, ACUCOC)<br>Medicaid - Community & State Hawaii (ACUHI, ACUHIEC)<br>Medicaid - Community & State Maryland (ACUMD)<br>Medicaid - Community & State Michigan (ACUMI)<br>Medicaid - Community & State New Jersey (PSI2300)<br>Medicaid - Community & State New Mexico (ACUNM)<br>Medicaid - Community & State New York (ACUNY, ACUNYM)<br>Medicaid - Community & State New York EPP (ACUNYEPP)<br>Medicaid - Community & State Pennsylvania CHIP (ACUPAC)<br>Medicaid - Community & State Rhode Island (ACURI)<br>Medicaid - Community & State Virginia (ACUVA, ACUVAC, ACUVAEC) |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 4/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                                 |                       |
|---------------------------------|-----------------------|
| Product Name:Vyndaqel, Vyndamax |                       |
| Approval Length                 | 12 month(s)           |
| Therapy Stage                   | Initial Authorization |
| Guideline Type                  | Prior Authorization   |

**Approval Criteria**

**1** - Diagnosis of transthyretin (ATTR)-mediated amyloidosis with cardiomyopathy (ATTR-CM)

**AND**

**2** - ONE of the following:

**2.1** Documentation that the patient has a pathogenic transthyretin (TTR) mutation (e.g., V30M)

**OR**

**2.2** Cardiac or noncardiac tissue biopsy demonstrating histologic confirmation of ATTR amyloid deposits

**OR**

**2.3** ALL of the following

**2.3.1** Echocardiogram or cardiac magnetic resonance imaging suggestive of amyloidosis

**AND**

**2.3.2** Radionuclide imaging (99mTc-DPD, 99mTc-PYP, or 99m Tc-HMDP) showing grade 2 or 3 cardiac uptake\*

**AND**

**2.3.3** Absence of light chain amyloidosis

**AND**

**3** - Patient has New York Heart Association (NYHA) Functional Class I, II, or III heart failure

**AND**

**4** - Physician attests that the patient has an N-terminal pro-B-type natriuretic peptide (NT-proBNP) level that, when combined with signs and symptoms, is considered definitive for a diagnosis of ATTR-CM

**AND**

**5** - ONE of the following:

History of heart failure, with at least one prior hospitalization for heart failure

Presence of clinical signs and symptoms of heart failure (e.g., dyspnea, edema)

**AND**

**6** - Prescribed by, or in consultation, with a cardiologist

**AND**

**7** - Patient is not receiving Vyndaqel/Vyndamax in combination with an RNA-targeted therapy for ATTR amyloidosis [i.e., Amvuttra (vutrisiran), Attruby (acoramadis), Onpattro (patisiran), Tegsedi (inotersen), or Wainua (eplontersen)]

|       |                                                   |
|-------|---------------------------------------------------|
| Notes | *May require prior authorization and notification |
|-------|---------------------------------------------------|

|                                                                                                                                              |                     |
|----------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Vyndaqel, Vyndamax                                                                                                              |                     |
| Approval Length                                                                                                                              | 12 month(s)         |
| Therapy Stage                                                                                                                                | Reauthorization     |
| Guideline Type                                                                                                                               | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation that the patient has experienced a positive clinical response to Vyndaqel or</p> |                     |

Vyndamax (e.g., improved symptoms, quality of life, slowing of disease progression, decreased hospitalizations, etc.)

**AND**

**2** - Documentation that patient continues to have New York Heart Association (NYHA) Functional Class I, II, or III heart failure

**AND**

**3** - Prescribed by or in consultation with a cardiologist

**AND**

**4** - Patient is not receiving Vyndaqel/Vyndamax in combination with an RNA-targeted therapy for ATTR amyloidosis [i.e., Amvuttra (vutrisiran), Attruby (acoramadis), Onpattro (patisiran), Tegsedi (inotersen), or Wainua (eplontersen)]

## 2 . Revision History

| Date     | Notes                                                                                                                                                   |
|----------|---------------------------------------------------------------------------------------------------------------------------------------------------------|
| 3/5/2025 | Updated formularies. Updated initial auth criteria. Removed criteria allowing for temporary combination therapy. Added examples of RNA-targeted therapy |

Vyvgart Hytrulo



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-432334                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Guideline Name</b> | Vyvgart Hytrulo                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Formulary</b>      | Medicaid - Community & State Colorado (ACUCO, ACUCOC)<br>Medicaid - Community & State Hawaii (ACUHI, ACUHIEC)<br>Medicaid - Community & State Maryland (ACUMD)<br>Medicaid - Community & State New Jersey (PSI2300)<br>Medicaid - Community & State New York (ACUNY, ACUNYM)<br>Medicaid - Community & State New York EPP (ACUNYEPP)<br>Medicaid - Community & State Pennsylvania CHIP (ACUPAC)<br>Medicaid - Community & State Rhode Island (ACURI)<br>Medicaid - Community & State Michigan (ACUMI)<br>Medicaid - Community & State Nebraska (ACUNE)<br>Medicaid - Community & State New Mexico (ACUNM)<br>Medicaid - Community & State Virginia (ACUVA, ACUVAC, ACUVAEC) |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 12/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                                                |                               |
|------------------------------------------------|-------------------------------|
| Product Name:Vyvgart Hytrulo prefilled syringe |                               |
| Diagnosis                                      | Generalized Myasthenia Gravis |
| Approval Length                                | 12 month(s)                   |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                       |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of generalized Myasthenia Gravis (gMG)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Positive serologic test for anti-acetylcholine receptor (AChR) antibodies</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Patient has a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of class II, III, or IV at initiation of therapy</p> <p style="text-align: center;"><b>AND</b></p> <p><b>4</b> - Patient has a Myasthenia Gravis Activities of Daily Living scale (MG-ADL) total score greater than or equal to 5 at initiation of therapy</p> <p style="text-align: center;"><b>AND</b></p> <p><b>5</b> - ONE of the following:</p> <p><b>5.1</b> History of failure of a minimum of two immunosuppressive agents over the course of at least 12 months (e.g., azathioprine, corticosteroids, cyclosporine, methotrexate, mycophenolate, etc.) as confirmed by claims history or submission of medical records</p> <p style="text-align: center;"><b>OR</b></p> <p><b>5.2</b> BOTH of the following:</p> |                       |

History of failure of at least one immunosuppressive therapy as confirmed by claims history or submission of medical records

Patient has required four or more courses of plasmapheresis/plasma exchanges and/or immune globulin over the course of at least 12 months without symptom control

**AND**

**6** - Patient is not receiving Vyvgart Hytrulo in combination with ANY of the following for treatment of the same indication:

A complement inhibitor [e.g., eculizumab, Ultomiris (ravulizumab), Zilbrysq (zilucoplan)]

Another neonatal Fc receptor (FcRn) blocker [e.g., Imaavy (nipocalimab), Rystiggo (rozanolixizumab)]

Immune globulin (e.g., Gammagard, Privigen, Hizentra)

**AND**

**7** - Prescribed by or in consultation with a neurologist

|                                                                                                                                                                                                                                                                                                        |                               |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|
| Product Name:Vyvgart Hytrulo prefilled syringe                                                                                                                                                                                                                                                         |                               |
| Diagnosis                                                                                                                                                                                                                                                                                              | Generalized Myasthenia Gravis |
| Approval Length                                                                                                                                                                                                                                                                                        | 12 month(s)                   |
| Therapy Stage                                                                                                                                                                                                                                                                                          | Reauthorization               |
| Guideline Type                                                                                                                                                                                                                                                                                         | Prior Authorization           |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Submission of medical records (e.g., chart notes, laboratory tests) demonstrating ALL of the following:</p> <p>Improvement and/or maintenance of at least a 2-point improvement (reduction in score) in the MG-ADL score from pre-treatment baseline</p> |                               |



Reduction in signs and symptoms of myasthenia gravis

Maintenance, reduction, or discontinuation of dose(s) of baseline immunosuppressive therapy (IST) prior to starting Vyvgart Hytrulo. Note: Add on, dose escalation of IST, or additional rescue therapy from baseline to treat myasthenia gravis or exacerbation of symptoms while on Vyvgart Hytrulo therapy will be considered as treatment failure

**AND**

**2** - Patient is not receiving Vyvgart Hytrulo in combination with ANY of the following for treatment of the same indication:

A complement inhibitor [e.g., eculizumab, Ultomiris (ravulizumab), Zilbrysq (zilucoplan)]

Another neonatal Fc receptor (FcRn) blocker [e.g., Imaavy (nipocalimab), Rystiggo (rozanolixizumab)]

Immune globulin (e.g., Gammagard, Privigen, Hizentra)

**AND**

**3** - Prescribed by or in consultation with a neurologist

|                                                                                                                                                                                   |                                                          |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------|
| Product Name:Vyvgart Hytrulo prefilled syringe                                                                                                                                    |                                                          |
| Diagnosis                                                                                                                                                                         | Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) |
| Approval Length                                                                                                                                                                   | 12 month(s)                                              |
| Therapy Stage                                                                                                                                                                     | Initial Authorization                                    |
| Guideline Type                                                                                                                                                                    | Prior Authorization                                      |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of chronic inflammatory demyelinating polyneuropathy (CIDP)</p> <p><b>AND</b></p> <p><b>2</b> - ALL of the following:</p> |                                                          |

**2.1** Progressive symptoms present for at least 2 months

**AND**

**2.2** Symptomatic polyradiculoneuropathy as indicated by progressive or relapsing motor or sensory impairment of more than one limb

**AND**

**2.3** Electrodiagnostic findings (consistent with EFNS/PNS guidelines for definite CIDP) indicating the presence of at least ONE of the following:

Motor distal latency prolongation in 2 nerves

Reduction of motor conduction velocity in 2 nerves

Prolongation of F-wave latency in 2 nerves

Absence of F-waves in at least 1 nerve

Partial motor conduction block of at least 1 motor nerve

Abnormal temporal dispersion in at least 2 nerves

Distal CMAP duration increase in at least 1 nerve

**AND**

**3** - ONE of the following:

**3.1** Failure (after a trial of at least two months) to a corticosteroid (e.g., prednisone, methylprednisolone) as confirmed by claims history or submission of medical records

**OR**

**3.2** History of contraindication or intolerance to a corticosteroid (please specify contraindication or intolerance)

**AND**

**4** - ONE of the following:

**4.1** Trial and failure (after a trial of at least three months) to an immune globulin (e.g., Gammagard, Privigen, Hizentra) with the maximally allowable and/or tolerated dose as confirmed by claims history or submission of medical records

**OR**

**4.2** BOTH of the following:

Intolerance to all immune globulins (e.g., Gammagard, Privigen, Hizentra) (please specify intolerance)

Dose has been adjusted or escalated to the maximally allowable and/or tolerated dose

**OR**

**4.3** Contraindication to ALL immune globulins (e.g., Gammagard, Privigen, Hizentra) (please specify contraindication)

**AND**

**5** - Patient is not receiving Vyvgart Hytrulo in combination with an immune globulin (e.g., Gammagard, Privigen, Hizentra) for treatment of the same indication

**AND**

**6** - Prescribed by or in consultation with a neurologist

|                                                |                                                          |
|------------------------------------------------|----------------------------------------------------------|
| Product Name:Vyvgart Hytrulo prefilled syringe |                                                          |
| Diagnosis                                      | Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) |
| Approval Length                                | 12 month(s)                                              |
| Therapy Stage                                  | Reauthorization                                          |

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Prior Authorization |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of a positive clinical response to Vyvgart Hytrulo as measured by an objective scale [e.g., Rankin, Modified Rankin, Medical Research Council (MRC) scale]</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Patient is not receiving Vyvgart Hytrulo in combination with an immune globulin (e.g., Gammagard, Privigen, Hizentra) used for treatment of the same indication</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Prescribed by or in consultation with a neurologist</p> |                     |

## 2 . Revision History

| Date      | Notes        |
|-----------|--------------|
| 11/4/2025 | New Program. |

Wainua



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-328241                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Guideline Name</b> | Wainua                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Formulary</b>      | Medicaid - Community & State Colorado (ACUCO, ACUCOC)<br>Medicaid - Community & State Hawaii (ACUHI, ACUHIEC)<br>Medicaid - Community & State Maryland (ACUMD)<br>Medicaid - Community & State Nebraska (ACUNE)<br>Medicaid - Community & State New Jersey (PSI2300)<br>Medicaid - Community & State New Mexico (ACUNM)<br>Medicaid - Community & State New York (ACUNY, ACUNYM)<br>Medicaid - Community & State New York EPP (ACUNYEPP)<br>Medicaid - Community & State Pennsylvania (ACUPA)<br>Medicaid - Community & State Pennsylvania CHIP (ACUPAC)<br>Medicaid - Community & State Rhode Island (ACURI)<br>Medicaid - Community & State Virginia (ACUVA, ACUVAC, ACUVAEC) |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 8/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                     |                       |
|---------------------|-----------------------|
| Product Name:Wainua |                       |
| Approval Length     | 12 month(s)           |
| Therapy Stage       | Initial Authorization |

| Guideline Type | Prior Authorization                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                | <p><b>Approval Criteria</b></p> <p><b>1 - BOTH of the following:</b></p> <p><b>1.1</b> Diagnosis of hereditary transthyretin-mediated (hATTR) amyloidosis with polyneuropathy</p> <p style="text-align: center;"><b>AND</b></p> <p><b>1.2</b> Documentation that the patient has a pathogenic transthyretin (TTR) mutation (e.g., V30M)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2 -</b> Prescribed by or in consultation with a neurologist</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3 -</b> Documentation of ONE of the following:</p> <p style="padding-left: 40px;">Patient has a baseline polyneuropathy disability (PND) score less than or equal to IIIb</p> <p style="padding-left: 40px;">Patient has a baseline familial amyloidotic polyneuropathy (FAP) Stage 1 or 2</p> <p style="padding-left: 40px;">Patient has a baseline neuropathy impairment (NIS) score greater than or equal to 10 and less than or equal to 130</p> <p style="text-align: center;"><b>AND</b></p> <p><b>4 -</b> Patient has NOT had a liver transplant</p> <p style="text-align: center;"><b>AND</b></p> <p><b>5 -</b> Presence of clinical signs and symptoms of the disease (e.g., peripheral sensorimotor polyneuropathy, autonomic neuropathy, motor disability, etc.)</p> |

**AND**

**6** - Patient is NOT receiving Wainua in combination with ONE of the following:

Oligonucleotide agents [e.g., Onpattro (patisiran), Amvuttra (vutrisiran), Tegsedi (inotersen)]

Transthyretin stabilizer [e.g., Vyndaqel/Vyndamax (tafamadis), Attruby (acoramidis)]

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                     |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Wainua                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                     |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 12 month(s)         |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation that the patient has experienced a positive clinical response to Wainua therapy (e.g., improved neurologic impairment, motor function, quality of life, slowing of disease progression, etc.)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Patient is NOT receiving Wainua in combination with ONE of the following:</p> <p>Oligonucleotide agents [e.g., Onpattro (patisiran), Amvuttra (vutrisiran), Tegsedi (inotersen)]</p> <p>Transthyretin stabilizer [e.g., Vyndaqel/Vyndamax (tafamadis), Attruby (acoramidis)]</p> |                     |

## 2 . Revision History

| Date | Notes |
|------|-------|
|------|-------|

|           |                                                                                                                   |
|-----------|-------------------------------------------------------------------------------------------------------------------|
| 7/15/2025 | Removed IN from formularies. No change to clinical criteria. See GL-328240 for state specific IN Wainua criteria. |
|-----------|-------------------------------------------------------------------------------------------------------------------|



Wakix



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-448243                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Guideline Name</b> | Wakix                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Formulary</b>      | Medicaid - Community & State Colorado (ACUCO, ACUCOC)<br>Medicaid - Community & State Hawaii (ACUHI, ACUHIEC)<br>Medicaid - Community & State New Jersey (PSI2300)<br>Medicaid - Community & State New York (ACUNY, ACUNYM)<br>Medicaid - Community & State New York EPP (ACUNYEPP)<br>Medicaid - Community & State Pennsylvania CHIP (ACUPAC)<br>Medicaid - Community & State Rhode Island (ACURI)<br>Medicaid - Community & State New Mexico (ACUNM) |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 12/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                    |                                                        |
|--------------------|--------------------------------------------------------|
| Product Name:Wakix |                                                        |
| Diagnosis          | Narcolepsy without Cataplexy (i.e., Narcolepsy Type 2) |
| Approval Length    | 12 month(s)                                            |
| Therapy Stage      | Initial Authorization                                  |
| Guideline Type     | Prior Authorization                                    |

### **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes, lab values) documenting a diagnosis of narcolepsy with BOTH of the following:

**1.1** The patient has daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least three months

**AND**

**1.2** A mean sleep latency of less than or equal to 8 minutes and two or more sleep onset rapid eye movement (REM) periods (SOREMPs) are found on a MSLT (Multiple Sleep Latency Test) performed according to standard techniques following a normal overnight polysomnogram. A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal polysomnogram may replace one of the SOREMPs on the MSLT

**AND**

**2** - Physician attestation that other causes of sleepiness have been ruled out or treated (including but not limited to obstructive sleep apnea, insufficient sleep syndrome, shift work, the effects of substances or medications or their withdrawal, sleep phase disorder, or other sleep disorders)

**AND**

**3** - ONE of the following:

**3.1** Failure to ALL of the following, as confirmed by claims history or submission of medical records:

An amphetamine-based stimulant (e.g., amphetamine, dextroamphetamine) OR a methylphenidate-based stimulant

Armodafinil (generic Nuvigil) OR modafinil (generic Provigil)

Sunosi (solriamfetol)

**OR**

**3.2** History of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):

An amphetamine-based stimulant (e.g., amphetamine, dextroamphetamine) OR a methylphenidate-based stimulant

Armodafinil (generic Nuvigil) OR modafinil (generic Provigil)

Sunosi (solriamfetol)

**OR**

**3.3** Patient has a history of or potential for a substance abuse disorder

**AND**

**4** - Prescribed by or in consultation with ONE of the following:

Neurologist

Psychiatrist

Pulmonologist

Sleep Medicine Specialist

|                                                                                                                                       |                                                        |
|---------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------|
| Product Name:Wakix                                                                                                                    |                                                        |
| Diagnosis                                                                                                                             | Narcolepsy without Cataplexy (i.e., Narcolepsy Type 2) |
| Approval Length                                                                                                                       | 12 month(s)                                            |
| Therapy Stage                                                                                                                         | Reauthorization                                        |
| Guideline Type                                                                                                                        | Prior Authorization                                    |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Reduction in symptoms of excessive daytime sleepiness associated with Wakix therapy</p> |                                                        |

|                    |                                                     |
|--------------------|-----------------------------------------------------|
| Product Name:Wakix |                                                     |
| Diagnosis          | Narcolepsy with Cataplexy (i.e., Narcolepsy Type 1) |
| Approval Length    | 12 month(s)                                         |
| Therapy Stage      | Initial Authorization                               |
| Guideline Type     | Prior Authorization                                 |

  

**Approval Criteria**

**1** - Submission of medical records (e.g., chart notes, lab values) documenting a diagnosis of narcolepsy with cataplexy (i.e., Narcolepsy Type 1) with BOTH of the following:

**1.1** The patient has daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least three months

**AND**

**1.2** A mean sleep latency of less than or equal to 8 minutes and two or more sleep onset rapid eye movement (REM) periods (SOREMPs) are found on a MSLT (Multiple Sleep Latency Test) performed according to standard techniques following a normal overnight polysomnogram. A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal polysomnogram may replace one of the SOREMPs on the MSLT

**AND**

**2** - Physician attestation to BOTH of the following:

**2.1** Patient has experienced cataplexy defined as more than one episode of sudden loss of muscle tone with retained consciousness

**AND**

**2.2** Other causes of sleepiness have been ruled out or treated (including but not limited to obstructive sleep apnea, insufficient sleep syndrome, shift work, the effects of substances or medications or their withdrawal, sleep phase disorder, or other sleep disorders)

**AND**

**3** - Prescribed by or in consultation with ONE of the following:

Neurologist

Psychiatrist

Pulmonologist

Sleep Medicine Specialist

Product Name:Wakix

|           |                                                     |
|-----------|-----------------------------------------------------|
| Diagnosis | Narcolepsy with Cataplexy (i.e., Narcolepsy Type 1) |
|-----------|-----------------------------------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                 |
|---------------|-----------------|
| Therapy Stage | Reauthorization |
|---------------|-----------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

### Approval Criteria

**1** - Reduction in frequency of cataplexy attacks associated with therapy

**OR**

**2** - Reduction in symptoms of excessive daytime sleepiness associated with therapy

## 2 . Revision History

| Date       | Notes                                                                          |
|------------|--------------------------------------------------------------------------------|
| 11/11/2025 | Combined formularies. No changes to clinical criteria. Minor cosmetic updates. |

Wegovy



## Prior Authorization Guideline

|                       |                                                   |
|-----------------------|---------------------------------------------------|
| <b>Guideline ID</b>   | GL-449243                                         |
| <b>Guideline Name</b> | Wegovy                                            |
| <b>Formulary</b>      | Medicaid - Community & State New Jersey (PSI2300) |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 12/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                                                                                                                        |                                                              |
|------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------|
| Product Name:Wegovy                                                                                                    |                                                              |
| Diagnosis                                                                                                              | Reduction in the risk of major adverse cardiovascular events |
| Approval Length                                                                                                        | 12 month(s)                                                  |
| Therapy Stage                                                                                                          | Initial Authorization                                        |
| Guideline Type                                                                                                         | Prior Authorization                                          |
| <b>Approval Criteria</b><br>1 - Treatment is being requested to reduce the risk of major adverse cardiovascular events |                                                              |

**AND**

**2** - Patient is 18 years of age or older

**AND**

**3** - Submission of medical records documenting ALL of the following:

**3.1** BMI (body mass index) greater than or equal to 27 kg/m<sup>2</sup> (kilograms per square meter)

**AND**

**3.2** Established cardiovascular disease as evidenced by ONE of the following:

**3.2.1** Prior myocardial infarction (MI)

**OR**

**3.2.2** Prior ischemic or hemorrhagic stroke

**OR**

**3.2.3** Symptomatic peripheral arterial disease (PAD) evidenced by ONE of the following:

Intermittent claudication with ankle-brachial index (ABI) less than 0.85 (at rest)

Peripheral arterial revascularization procedure

Amputation due to atherosclerotic disease

**AND**

**4** - Used in combination with a reduced calorie diet and increased physical activity

**AND**

**5** - ONE of the following:

**5.1** For patients with history of MI, ONE of the following:

**5.1.1** Patient is on therapy from each of the following classes (as confirmed by claims history or submission of medical records):

Cholesterol lowering medication (e.g., statin, PCSK9i)

Beta blocker (i.e., carvedilol, metoprolol, or bisoprolol)

Angiotensin-converting enzyme inhibitor (ACE-I)/angiotensin II receptor blocker (ARB)/angiotensin II receptor blocker neprilysin inhibitor (ARNI)

Antiplatelet (e.g., aspirin, clopidogrel)

**OR**

**5.1.2** Patient has a history of intolerance or contraindication to ALL of the following therapeutic classes (please specify intolerance or contraindication):

Cholesterol lowering medication (e.g., statin, PCSK9i)

Beta blocker (i.e., carvedilol, metoprolol, or bisoprolol)

Angiotensin-converting enzyme inhibitor (ACE-I)/angiotensin II receptor blocker (ARB)/angiotensin II receptor blocker neprilysin inhibitor (ARNI)

Antiplatelet (e.g., aspirin, clopidogrel)

**OR**

**5.2** For patients with history of ischemic or hemorrhagic stroke, or symptomatic PAD, ONE of the following:

**5.2.1** Patient is on therapy from each of the following classes (as confirmed by claims history or submission of medical records):



Cholesterol lowering medication (e.g., statin, PCSK9i)

Angiotensin-converting enzyme inhibitor (ACE-I)/angiotensin II receptor blocker (ARB)/angiotensin II receptor blocker neprilysin inhibitor (ARNI)

Antiplatelet (e.g., aspirin, clopidogrel)

**OR**

**5.2.2** Patient has a history of intolerance or contraindication to ALL of the following therapeutic classes (please specify intolerance or contraindication):

Cholesterol lowering medication (e.g., statin, PCSK9i)

Angiotensin-converting enzyme inhibitor (ACE-I)/angiotensin II receptor blocker (ARB)/angiotensin II receptor blocker neprilysin inhibitor (ARNI)

Antiplatelet (e.g., aspirin, clopidogrel)

**AND**

**6** - Patient does NOT have New York Heart Association class IV heart failure

**AND**

**7** - ONE of the following:

**7.1** HgA1c less than 6.5%

**OR**

**7.2** BOTH of the following:

Diagnosis of diabetes or HgA1c greater than or equal to 6.5%

There is a reason or special circumstance why patient cannot use a commercially available semaglutide product indicated for type 2 diabetes mellitus

|                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                              |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------|
| Product Name:Wegovy                                                                                                                                                                                                                                                                                                                                                                                                  |                                                              |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                            | Reduction in the risk of major adverse cardiovascular events |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                      | 12 month(s)                                                  |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                        | Reauthorization                                              |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                       | Prior Authorization                                          |
| <p><b>Approval Criteria</b></p> <p>1 - BMI (body mass index) greater than or equal to 27 kg/m<sup>2</sup> (kilograms per square meter)</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Used in combination with a reduced calorie diet and increased physical activity</p> <p style="text-align: center;"><b>AND</b></p> <p>3 - Patient does NOT have New York Heart Association class IV heart failure</p> |                                                              |

|                                                                                                                                                                                                                                                                                                           |                                                                      |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------|
| Product Name:Wegovy                                                                                                                                                                                                                                                                                       |                                                                      |
| Diagnosis                                                                                                                                                                                                                                                                                                 | Noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH) |
| Approval Length                                                                                                                                                                                                                                                                                           | 12 month(s)                                                          |
| Therapy Stage                                                                                                                                                                                                                                                                                             | Initial Authorization                                                |
| Guideline Type                                                                                                                                                                                                                                                                                            | Prior Authorization                                                  |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of metabolic dysfunction-associated steatohepatitis (MASH) [formerly known as nonalcoholic steatohepatitis (NASH)]</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Disease is fibrosis stage F2 or F3 as confirmed by ONE of the following:</p> |                                                                      |

Liver stiffness measurement (LSM) by vibration-controlled transient elastography (VCTE) (e.g., FibroScan)

LSM by magnetic resonance elastography (MRE)

Liver biopsy within the past 12 months

**AND**

**3** - Patient has received comprehensive counseling regarding lifestyle modification (e.g., dietary or caloric restriction, exercise, behavioral support, community-based program)

**AND**

**4** - Provider attests Wegovy will not be initiated at the same time as Rezdiffra (resmetirom)

**AND**

**5** - Prescribed by or in consultation with ONE of the following:

Endocrinologist

Gastroenterologist

Hepatologist

|                          |                                                                      |
|--------------------------|----------------------------------------------------------------------|
| Product Name:Wegovy      |                                                                      |
| Diagnosis                | Noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH) |
| Approval Length          | 12 month(s)                                                          |
| Therapy Stage            | Reauthorization                                                      |
| Guideline Type           | Prior Authorization                                                  |
| <b>Approval Criteria</b> |                                                                      |

**1** - Documentation of positive clinical response to Wegovy therapy (e.g., improvement in or stabilization of fibrosis)

**AND**

**2** - Patient has not progressed to cirrhosis

**AND**

**3** - Prescribed by or in consultation with ONE of the following:

Endocrinologist

Gastroenterologist

Hepatologist

Product Name:Wegovy

|           |             |
|-----------|-------------|
| Diagnosis | Weight Loss |
|-----------|-------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

### Approval Criteria

**1** - Wegovy when used solely for the treatment of weight loss is excluded and is to be denied as a benefit exclusion

## 2 . Revision History

| Date       | Notes                                                                                                                                                          |
|------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 11/14/2025 | Updated indication to "Reduction in the risk of major adverse cardiovascular events". Minor cosmetic updates. Updated criteria to add new indication for MASH. |

Welireg



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-401254                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Guideline Name</b> | Welireg                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Formulary</b>      | Medicaid - Community & State Colorado (ACUCO, ACUCOC)<br>Medicaid - Community & State Hawaii (ACUHI, ACUHIEC)<br>Medicaid - Community & State Maryland (ACUMD)<br>Medicaid - Community & State New Jersey (PSI2300)<br>Medicaid - Community & State New York (ACUNY, ACUNYM)<br>Medicaid - Community & State New York EPP (ACUNYEPP)<br>Medicaid - Community & State Pennsylvania CHIP (ACUPAC)<br>Medicaid - Community & State Rhode Island (ACURI)<br>Medicaid - Community & State New Mexico (ACUNM)<br>Medicaid - Community & State Virginia (ACUVA, ACUVAC, ACUVAEC)<br>Medicaid - Community & State Washington (ACUWA, ACUWAAHE, ACUWAC) |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 10/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                       |                                 |
|-----------------------|---------------------------------|
| Product Name: Welireg |                                 |
| Diagnosis             | Von Hippel-Lindau (VHL) Disease |
| Approval Length       | 12 month(s)                     |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                       |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of von Hippel-Lindau (VHL) disease</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Patient requires therapy for ONE of the following:</p> <p style="padding-left: 40px;">Renal cell carcinoma (RCC)</p> <p style="padding-left: 40px;">Central nervous system (CNS) hemangioblastoma</p> <p style="padding-left: 40px;">Pancreatic neuroendocrine tumor (pNET)</p> <p style="text-align: center;"><b>AND</b></p> <p>3 - Patient does not require immediate surgery</p> |                       |

|                                                                                                                                           |                               |
|-------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|
| Product Name: Welireg                                                                                                                     |                               |
| Diagnosis                                                                                                                                 | Advanced Renal Cell Carcinoma |
| Approval Length                                                                                                                           | 12 month(s)                   |
| Therapy Stage                                                                                                                             | Initial Authorization         |
| Guideline Type                                                                                                                            | Prior Authorization           |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of advanced renal cell carcinoma (RCC)</p> <p style="text-align: center;"><b>AND</b></p> |                               |

**2** - Disease has progressed after treatment with BOTH of the following:

**2.1** Programmed death receptor 1 (PD-1) or programmed death ligand 1 (PD-L1) checkpoint inhibitor [e.g., Keytruda (pembrolizumab), Opdivo (nivolumab)]

**AND**

**2.2** Vascular endothelial growth factor tyrosine kinase inhibitor (VEGF-TKI) [e.g., Cabometyx (cabozantinib), Inlyta (axitinib), Lenvima (lenvatinib)]

|                                                                                                                                                                                                                                    |                                |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|
| Product Name: Welireg                                                                                                                                                                                                              |                                |
| Diagnosis                                                                                                                                                                                                                          | Pheochromocytoma/Paraganglioma |
| Approval Length                                                                                                                                                                                                                    | 12 month(s)                    |
| Therapy Stage                                                                                                                                                                                                                      | Initial Authorization          |
| Guideline Type                                                                                                                                                                                                                     | Prior Authorization            |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of pheochromocytoma or paraganglioma (PPGL)</p> <p><b>AND</b></p> <p><b>2</b> - Disease is ONE of the following:</p> <p>Advanced</p> <p>Unresectable</p> <p>Metastatic</p> |                                |

|                       |                       |
|-----------------------|-----------------------|
| Product Name: Welireg |                       |
| Diagnosis             | All above indications |
| Approval Length       | 12 month(s)           |

|                                                                                                               |                     |
|---------------------------------------------------------------------------------------------------------------|---------------------|
| Therapy Stage                                                                                                 | Reauthorization     |
| Guideline Type                                                                                                | Prior Authorization |
| <b>Approval Criteria</b><br><b>1</b> - Patient does not show evidence of disease progression while on Welireg |                     |

|                                                                                                                                            |                           |
|--------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name: Welireg                                                                                                                      |                           |
| Diagnosis                                                                                                                                  | NCCN Recommended Regimens |
| Approval Length                                                                                                                            | 12 month(s)               |
| Therapy Stage                                                                                                                              | Initial Authorization     |
| Guideline Type                                                                                                                             | Prior Authorization       |
| <b>Approval Criteria</b><br><b>1</b> - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium |                           |

|                                                                                                       |                           |
|-------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name: Welireg                                                                                 |                           |
| Diagnosis                                                                                             | NCCN Recommended Regimens |
| Approval Length                                                                                       | 12 month(s)               |
| Therapy Stage                                                                                         | Reauthorization           |
| Guideline Type                                                                                        | Prior Authorization       |
| <b>Approval Criteria</b><br><b>1</b> - Documentation of positive clinical response to Welireg therapy |                           |

## 2 . Revision History



UnitedHealthcare Community Plan of New Jersey – Clinical Pharmacy Guidelines

| Date      | Notes                                                                                |
|-----------|--------------------------------------------------------------------------------------|
| 9/17/2025 | Added section for pheochromocytoma/Paraganglioma. Added NM, V A, and WA formularies. |

Winrevair



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-152465                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Guideline Name</b> | Winrevair                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Formulary</b>      | Medicaid - Community & State Colorado (ACUCO, ACUCOC)<br>Medicaid - Community & State Hawaii (ACUHI, ACUHIEC)<br>Medicaid - Community & State Maryland (ACUMD)<br>Medicaid - Community & State New Jersey (PSI2300)<br>Medicaid - Community & State New York EPP (ACUNYEPP)<br>Medicaid - Community & State New York (ACUNY, ACUNYM)<br>Medicaid - Community & State Pennsylvania CHIP (ACUPAC)<br>Medicaid - Community & State Rhode Island (ACURI) |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 9/1/2024 |
|-----------------|----------|

## 1 . Criteria

|                         |                       |
|-------------------------|-----------------------|
| Product Name: Winrevair |                       |
| Approval Length         | 12 month(s)           |
| Therapy Stage           | Initial Authorization |
| Guideline Type          | Prior Authorization   |
|                         |                       |

**Approval Criteria**

**1** - One of the following:

**1.1** All of the following:

**1.1.1** Diagnosis of pulmonary arterial hypertension (PAH)

**AND**

**1.1.2** PAH has been confirmed by right heart catheterization

**AND**

**1.1.3** Prescriber attestation that other types of pulmonary hypertension (PH) are excluded as a diagnosis

**AND**

**1.1.4** Pulmonary arterial hypertension is symptomatic

**OR**

**1.2** Both of the following:

**1.2.1** Diagnosis of pulmonary arterial hypertension

**AND**

**1.2.2** Patient is currently on Winrevair therapy as documented by claims history or submission of medical records

**AND**

**2** - One of the following:

**2.1** Both of the following:

**2.1.1** Patient has a cardiopulmonary comorbidity (e.g., obesity, hypertension, diabetes mellitus, coronary heart disease)

**AND**

**2.1.2** Patient is currently taking at least ONE of the following oral therapies:

Endothelin receptor antagonist (ERA) [e.g., ambrisentan, bosentan, Opsumit (macitentan)]

Phosphodiesterase-5 inhibitor (PDE5i) (e.g., sildenafil, tadalafil)

**OR**

**2.2** Both of the following:

**2.2.1** Patient does not have a cardiopulmonary comorbidity (e.g., obesity, hypertension, diabetes mellitus, coronary heart disease)

**AND**

**2.2.2** Patient is currently taking oral combination therapy with BOTH of the following:

**2.2.2.1** Endothelin receptor antagonist (ERA) [e.g., ambrisentan, bosentan, Opsumit (macitentan)]

**AND**

**2.2.2.2** One of the following:

Phosphodiesterase-5 inhibitor (PDE5i) (e.g., sildenafil, tadalafil)

Soluble guanylate cyclase stimulator (sGC) [e.g., Adempas (riociguat)]

**AND**

**3** - Prescribed by, or in consultation with, a cardiologist, pulmonologist, or rheumatologist

|                                                                                                                                                                                                                                                                                                                                                                                                                            |                     |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Winrevair                                                                                                                                                                                                                                                                                                                                                                                                     |                     |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                            | 12 month(s)         |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                              | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                             | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of a positive clinical response to Winrevair therapy [e.g., improvement in symptoms of right heart failure, exercise tolerance, six-minute walk distance (6MWD), resting and ambulatory oximetry]</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Prescribed by, or in consultation with, a cardiologist, pulmonologist, or rheumatologist</p> |                     |

## 2 . Revision History

| Date      | Notes |
|-----------|-------|
| 8/21/2024 | New.  |

Xalkori



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-228226                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Guideline Name</b> | Xalkori                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Formulary</b>      | Medicaid - Community & State Colorado (ACUCO, ACUCOC)<br>Medicaid - Community & State Hawaii (ACUHI, ACUHIEC)<br>Medicaid - Community & State Indiana (ACUIN)<br>Medicaid - Community & State Maryland (ACUMD)<br>Medicaid - Community & State New Jersey (PSI2300)<br>Medicaid - Community & State New Mexico (ACUNM)<br>Medicaid - Community & State New York (ACUNY, ACUNYM)<br>Medicaid - Community & State New York EPP (ACUNYEPP)<br>Medicaid - Community & State Pennsylvania CHIP (ACUPAC)<br>Medicaid - Community & State Rhode Island (ACURI)<br>Medicaid - Community & State Virginia (ACUVA, ACUVAC, ACUVAEC) |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 5/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                      |                                          |
|----------------------|------------------------------------------|
| Product Name:Xalkori |                                          |
| Diagnosis            | Inflammatory Myofibroblastic Tumor (IMT) |
| Approval Length      | 12 month(s)                              |
| Therapy Stage        | Initial Authorization                    |

|                                                                                                                                                      |                     |
|------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Guideline Type                                                                                                                                       | Prior Authorization |
| <b>Approval Criteria</b><br><br><b>1</b> - Diagnosis of inflammatory myofibroblastic tumor (IMT) with anaplastic lymphoma kinase (ALK) translocation |                     |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                    |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|
| Product Name:Xalkori                                                                                                                                                                                                                                                                                                                                                                                                                               |                                    |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                          | Non-Small Cell Lung Cancer (NSCLC) |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                    | 12 month(s)                        |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                      | Initial Authorization              |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                     | Prior Authorization                |
| <b>Approval Criteria</b><br><br><b>1</b> - Diagnosis of non-small cell lung cancer (NSCLC)<br><br><div style="text-align: center;"><b>AND</b></div><br><br><b>2</b> - Disease is ONE of the following:<br><br>Metastatic<br><br>Recurrent<br><br>Advanced<br><br><div style="text-align: center;"><b>AND</b></div><br><br><b>3</b> - ONE of the following:<br><br>Tumor is anaplastic lymphoma kinase (ALK)-positive<br><br>Tumor is ROS1-positive |                                    |

Tumor is positive for mesenchymal-epithelial transition (MET) amplification

Tumor is positive for MET exon 14 skipping mutation

|                                                                                                                                                                                                                                                                                                                                                        |                                      |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|
| Product Name:Xalkori                                                                                                                                                                                                                                                                                                                                   |                                      |
| Diagnosis                                                                                                                                                                                                                                                                                                                                              | Central Nervous System (CNS) Cancers |
| Approval Length                                                                                                                                                                                                                                                                                                                                        | 12 month(s)                          |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                          | Initial Authorization                |
| Guideline Type                                                                                                                                                                                                                                                                                                                                         | Prior Authorization                  |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of metastatic brain cancer from non-small cell lung cancer (NSCLC)</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - ONE of the following:</p> <p style="padding-left: 40px;">Tumor is anaplastic lymphoma kinase (ALK)-positive</p> <p style="padding-left: 40px;">Tumor is ROS1-positive</p> |                                      |

|                                                                                        |                                |
|----------------------------------------------------------------------------------------|--------------------------------|
| Product Name:Xalkori                                                                   |                                |
| Diagnosis                                                                              | Anaplastic Large Cell Lymphoma |
| Approval Length                                                                        | 12 month(s)                    |
| Therapy Stage                                                                          | Initial Authorization          |
| Guideline Type                                                                         | Prior Authorization            |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of anaplastic large cell lymphoma</p> |                                |



**AND**

**2** - Tumor is anaplastic lymphoma kinase (ALK)-positive

**AND**

**3** - Disease is relapsed or refractory

|                                                                                                                                                                                                                                                                                                  |                       |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Xalkori                                                                                                                                                                                                                                                                             |                       |
| Diagnosis                                                                                                                                                                                                                                                                                        | Histiocytic Neoplasms |
| Approval Length                                                                                                                                                                                                                                                                                  | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                    | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                   | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of ONE of the following:</p> <p>Langerhans Cell Histiocytosis</p> <p>Erdheim-Chester Disease</p> <p>Rosai-Dorfman Disease</p> <p><b>AND</b></p> <p><b>2</b> - Disease is positive for anaplastic lymphoma kinase (ALK) rearrangement</p> |                       |

|                      |                       |
|----------------------|-----------------------|
| Product Name:Xalkori |                       |
| Diagnosis            | Melanoma              |
| Approval Length      | 12 month(s)           |
| Therapy Stage        | Initial Authorization |

|                                                                                                                                                                                                                                                                                                                                                                                                                            |                     |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                             | Prior Authorization |
| <b>Approval Criteria</b><br><br><b>1</b> - Diagnosis of metastatic or unresectable cutaneous melanoma<br><br><p style="text-align: center;"><b>AND</b></p> <b>2</b> - Disease is ROS1 gene fusion-positive<br><br><p style="text-align: center;"><b>AND</b></p> <b>3</b> - Used as second-line or subsequent therapy for disease progression, intolerance, and/or projected risk of progression with BRAF-targeted therapy |                     |

|                                                                                                                           |                                                                                                                                                                                     |
|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Product Name:Xalkori                                                                                                      |                                                                                                                                                                                     |
| Diagnosis                                                                                                                 | Inflammatory Myofibroblastic Tumor (IMT), Non-Small Cell Lung Cancer (NSCLC), Central Nervous System (CNS) Cancers, Anaplastic Large Cell Lymphoma, Histiocytic Neoplasms, Melanoma |
| Approval Length                                                                                                           | 12 month(s)                                                                                                                                                                         |
| Therapy Stage                                                                                                             | Reauthorization                                                                                                                                                                     |
| Guideline Type                                                                                                            | Prior Authorization                                                                                                                                                                 |
| <b>Approval Criteria</b><br><br><b>1</b> - Patient does not show evidence of progressive disease while on Xalkori therapy |                                                                                                                                                                                     |

|                      |                           |
|----------------------|---------------------------|
| Product Name:Xalkori |                           |
| Diagnosis            | NCCN Recommended Regimens |
| Approval Length      | 12 month(s)               |
| Therapy Stage        | Initial Authorization     |
| Guideline Type       | Prior Authorization       |

**Approval Criteria**

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

|                                                                                                           |                           |
|-----------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Xalkori                                                                                      |                           |
| Diagnosis                                                                                                 | NCCN Recommended Regimens |
| Approval Length                                                                                           | 12 month(s)               |
| Therapy Stage                                                                                             | Reauthorization           |
| Guideline Type                                                                                            | Prior Authorization       |
| <p><b>Approval Criteria</b></p> <p>1 - Documentation of positive clinical response to Xalkori therapy</p> |                           |

## 2 . Revision History

| Date      | Notes               |
|-----------|---------------------|
| 3/27/2025 | Updated formularies |

Xarelto



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-208213                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Guideline Name</b> | Xarelto                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Formulary</b>      | Medicaid - Community & State Colorado (ACUCO, ACUCOC)<br>Medicaid - Community & State Hawaii (ACUHI, ACUHIEC)<br>Medicaid - Community & State Maryland (ACUMD)<br>Medicaid - Community & State New Jersey (PSI2300)<br>Medicaid - Community & State New Mexico (ACUNM)<br>Medicaid - Community & State New York (ACUNY, ACUNYM)<br>Medicaid - Community & State New York EPP (ACUNYEPP)<br>Medicaid - Community & State Pennsylvania CHIP (ACUPAC)<br>Medicaid - Community & State Rhode Island (ACURI) |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 4/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                                                                            |                                                 |
|----------------------------------------------------------------------------|-------------------------------------------------|
| Product Name:Xarelto tablets, Xarelto oral suspension, generic rivaroxaban |                                                 |
| Diagnosis                                                                  | Continuation of Therapy Upon Hospital Discharge |
| Approval Length                                                            | 35 Day(s)                                       |
| Guideline Type                                                             | Prior Authorization                             |

**Approval Criteria**

1 - Xarelto will be approved as continuation of therapy upon hospital discharge

Product Name:Xarelto tablets, Xarelto oral suspension, generic rivaroxaban

|           |                                                                                                      |
|-----------|------------------------------------------------------------------------------------------------------|
| Diagnosis | Stroke and Systemic Embolism Prevention in Adult Patients with Non-Valvular Atrial Fibrillation (AF) |
|-----------|------------------------------------------------------------------------------------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

1 - Diagnosis of atrial fibrillation (AF)

**AND**

2 - Patient does not have an artificial heart valve

**AND**

3 - ONE of the following:

Failure to Eliquis as confirmed by claims history or submission of medical records

History of contraindication or intolerance to Eliquis (please specify contraindication or intolerance)

Continuation of prior Xarelto therapy

Product Name:Xarelto tablets, Xarelto oral suspension, generic rivaroxaban

|           |                                                                                                                              |
|-----------|------------------------------------------------------------------------------------------------------------------------------|
| Diagnosis | Prophylaxis of Venous Thromboembolism (VTE) after Orthopedic Surgery (Hip Replacement or Knee Replacement) in Adult Patients |
|-----------|------------------------------------------------------------------------------------------------------------------------------|

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                     |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 35 Day(s)           |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1 - ONE of the following:</b></p> <p><b>1.1</b> Patient has or is scheduled to have total knee replacement surgery</p> <p style="text-align: center;"><b>OR</b></p> <p><b>1.2</b> Patient has or is scheduled to have total hip replacement surgery</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2 - Patient does not have an artificial heart valve</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>3 - ONE of the following:</b></p> <p><b>3.1</b> Xarelto is being prescribed as continuation of therapy following hospitalization after orthopedic surgery</p> <p style="text-align: center;"><b>OR</b></p> <p><b>3.2</b> Provider provides reason or special circumstance why the patient is unable to use Eliquis</p> |                     |

|                                                                            |                                                                                      |
|----------------------------------------------------------------------------|--------------------------------------------------------------------------------------|
| Product Name:Xarelto tablets, Xarelto oral suspension, generic rivaroxaban |                                                                                      |
| Diagnosis                                                                  | Treatment of Deep Vein Thrombosis (DVT) or Pulmonary Embolism (PE) in Adult Patients |
| Approval Length                                                            | 12 month(s)                                                                          |
| Guideline Type                                                             | Prior Authorization                                                                  |

**Approval Criteria**

**1** - Diagnosis of ONE of the following:

Deep vein thrombosis (DVT)

Pulmonary embolism (PE)

**AND**

**2** - Patient does not have an artificial heart valve

**AND**

**3** - ONE of the following:

Failure to Eliquis as confirmed by claims history or submission of medical records

History on intolerance or contraindication to Eliquis (please specify intolerance or contraindication)

Continuation of prior Xarelto therapy

|                                                                                               |                                                                                                                 |
|-----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------|
| Product Name:Xarelto tablets, Xarelto oral suspension, generic rivaroxaban                    |                                                                                                                 |
| Diagnosis                                                                                     | Reduction in the Risk of Recurrence of Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE) in Adult Patients |
| Approval Length                                                                               | 12 month(s)                                                                                                     |
| Guideline Type                                                                                | Prior Authorization                                                                                             |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Previous diagnosis of ONE of the following:</p> |                                                                                                                 |

Deep vein thrombosis (DVT)

Pulmonary embolism (PE)

**AND**

**2** - Patient does not have an artificial heart valve

**AND**

**3** - Patient must have been treated with an anticoagulant [e.g., warfarin, Eliquis (apixaban)] for at least 6 months prior to request as confirmed by claims history or submission of medical records

**AND**

**4** - ONE of the following:

**4.1** Failure to Eliquis as confirmed by claims history or submission of medical records

**OR**

**4.2** History of intolerance or contraindication to Eliquis (please specify intolerance or contraindication)

**OR**

**4.3** Continuation of prior Xarelto therapy

| Product Name:Xarelto tablets, Xarelto oral suspension, generic rivaroxaban |                                                                                                                                                                                                                         |
|----------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Diagnosis                                                                  | Reduction in the Risk of Major Cardiovascular Events [Cardiovascular (CV) Death, Myocardial Infarction (MI) and Stroke] in Adult Patients with Chronic Coronary Artery Disease (CAD) or Peripheral Artery Disease (PAD) |
| Approval Length                                                            | 12 month(s)                                                                                                                                                                                                             |



| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                    | Prior Authorization |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of ONE of the following:</p> <p>Chronic coronary artery disease (CAD)</p> <p>Peripheral artery disease (PAD)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Patient does not have an artificial heart valve</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Patient is on concurrent aspirin therapy</p> |                     |

|                                                                                                                                                                                                                                     |                                                                                                                                                         |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------|
| Product Name:Xarelto tablets, Xarelto oral suspension, generic rivaroxaban                                                                                                                                                          |                                                                                                                                                         |
| Diagnosis                                                                                                                                                                                                                           | Prophylaxis of Venous Thromboembolism (VTE) in Acutely Ill Medical Adult Patients at Risk for Thromboembolic Complications Not at High Risk of Bleeding |
| Approval Length                                                                                                                                                                                                                     | 2 month(s)                                                                                                                                              |
| Guideline Type                                                                                                                                                                                                                      | Prior Authorization                                                                                                                                     |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Patient was admitted to the hospital for an acute medical illness</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Patient does not have an artificial heart valve</p> |                                                                                                                                                         |

**AND**

**3** - Patient is at risk of thromboembolic complications due to moderate or severe restricted mobility

**AND**

**4** - Patient is not at high risk of bleeding

Product Name:Xarelto tablets, Xarelto oral suspension, generic rivaroxaban

|           |                                                                                                   |
|-----------|---------------------------------------------------------------------------------------------------|
| Diagnosis | Thromboprophylaxis in Pediatric Patients with Congenital Heart Disease After the Fontan Procedure |
|-----------|---------------------------------------------------------------------------------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

### Approval Criteria

**1** - Diagnosis of congenital heart disease

**AND**

**2** - Patient does not have an artificial heart valve

**AND**

**3** - Patient is at risk of thromboembolic complications due to Fontan procedure

**AND**

**4** - Patient is 2 years to 17 years of age

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|
| Product Name:Xarelto tablets, Xarelto oral suspension, generic rivaroxaban                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                   |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Treatment of VTE and Reduction in the Risk of Recurrent VTE in Pediatric Patients |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 12 month(s)                                                                       |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Prior Authorization                                                               |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - The requested medication is being used for the treatment of venous thromboembolism (VTE) or the reduction in the risk of recurrent VTE</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Patient does not have an artificial heart valve</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Patient has received at least 5 days of initial parenteral anticoagulant treatment</p> <p style="text-align: center;"><b>AND</b></p> <p><b>4</b> - Patient is 0 years to 17 years of age</p> |                                                                                   |

## 2 . Revision History

| Date     | Notes                                                                                   |
|----------|-----------------------------------------------------------------------------------------|
| 3/5/2025 | Updated formularies. Added generic rixaroxaban. Removed step through Savaysa throughout |

Xdemvy



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-143401                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Guideline Name</b> | Xdemvy                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Formulary</b>      | Medicaid - Community & State Colorado (ACUCO, ACUCOC)<br>Medicaid - Community & State Hawaii (ACUHI, ACUHIEC)<br>Medicaid - Community & State Maryland (ACUMD)<br>Medicaid - Community & State New Jersey (PSI2300)<br>Medicaid - Community & State New York (ACUNY, ACUNYM)<br>Medicaid - Community & State New York EPP (ACUNYEPP)<br>Medicaid - Community & State Pennsylvania CHIP (ACUPAC)<br>Medicaid - Community & State Rhode Island (ACURI) |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 4/1/2024 |
|-----------------|----------|

## 1 . Criteria

|                          |                     |
|--------------------------|---------------------|
| Product Name:Xdemvy      |                     |
| Approval Length          | 6 Week(s)           |
| Guideline Type           | Prior Authorization |
| <b>Approval Criteria</b> |                     |

**1** - Diagnosis of Demodex blepharitis

**AND**

**2** - Patient demonstrates ONE of the following signs of Demodex infestation:

Cylindrical cuff at the root of the eyelashes

Lid margin erythema

Eyelash anomalies (e.g., eyelash misdirection, eyelash loss)

**AND**

**3** - Patient demonstrates TWO of the following symptoms of Demodex infestation:

Itching/Burning

Foreign body sensation

Crusting/matted lashes

Blurry vision

Discomfort/irritation

Tearing/lacrimation

Dryness

Purulence/discharge

**AND**

**4** - Patient is practicing good eye-lid hygiene (e.g., non-prescription tree-tea oil)

**AND**

**5** - Prescribed by or in consultation with ONE of the following:

Ophthalmologist

Optometrist

## 2 . Revision History

| Date      | Notes                                                                                                                                                                                       |
|-----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 2/22/2024 | Updated criteria to include eyelash loss as an example of eyelash anomalies and added tearing/lacrimation, dryness, and purulence/discharge to the list of symptoms of Demodex infestation. |

Xeljanz, Xeljanz XR, Xeljanz Oral Solution



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-208200                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Guideline Name</b> | Xeljanz, Xeljanz XR, Xeljanz Oral Solution                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Formulary</b>      | Medicaid - Community & State Colorado (ACUCO, ACUCOC)<br>Medicaid - Community & State Hawaii (ACUHI, ACUHIEC)<br>Medicaid - Community & State Maryland (ACUMD)<br>Medicaid - Community & State New Jersey (PSI2300)<br>Medicaid - Community & State New Mexico (ACUNM)<br>Medicaid - Community & State New York (ACUNY, ACUNYM)<br>Medicaid - Community & State Pennsylvania CHIP (ACUPAC)<br>Medicaid - Community & State Rhode Island (ACURI) |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 4/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                                       |                           |
|---------------------------------------|---------------------------|
| Product Name:Xeljanz tabs, Xeljanz XR |                           |
| Diagnosis                             | Rheumatoid Arthritis (RA) |
| Approval Length                       | 12 month(s)               |
| Therapy Stage                         | Initial Authorization     |
| Guideline Type                        | Prior Authorization       |

## **Approval Criteria**

**1** - ALL of the following:

**1.1** Diagnosis of moderately to severely active rheumatoid arthritis (RA)

**AND**

**1.2** One of the following:

**1.2.1** Failure to a 3 month trial of one non-biologic disease modifying anti-rheumatic drug (DMARD) [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine] at maximally indicated doses as confirmed by claims history or submission of medical records

**OR**

**1.2.2** History of intolerance or contraindication to one non-biologic DMARD [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine] (please specify intolerance or contraindication)

**OR**

**1.2.3** Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of rheumatoid arthritis as confirmed by claims history or submission of medical records [e.g., Enbrel (etanercept), Cimzia (certolizumab), adalimumab, Simponi (golimumab), Orencia (abatacept), Olumiant (baricitinib), Rinvoq (upadacitinib)]

**AND**

**1.3** BOTH of the following:

**1.3.1** ONE of the following:

**1.3.1.1** Failure to ALL of the following as confirmed by claims history or submission of medical records:

One of the preferred adalimumab products\*



Enbrel (etanercept)

Tyenne (tocilizumab-aazg)

**OR**

**1.3.1.2** History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication):

One of the preferred adalimumab products\*

Enbrel (etanercept)

Tyenne (tocilizumab-aazg)

**OR**

**1.3.1.3** Patient has a documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-V-TR 300.29 for specific phobia diagnostic criteria)

**AND**

**1.3.2** One of the following:

**1.3.2.1** Failure to Olumiant (baricitinib) as confirmed by claims history or submission of medical records

**OR**

**1.3.2.2** History of intolerance or contraindication to Olumiant (baricitinib) (please specify intolerance or contraindication)

**AND**

**1.4** Patient is NOT receiving Xeljanz/Xeljanz XR in combination with either of the following:

Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Rinvoq (upadacitinib), Olumiant (baricitinib)]

Potent immunosuppressant (e.g., azathioprine or cyclosporine)

**AND**

**1.5** Prescribed by or in consultation with a rheumatologist

**OR**

**2** - ALL of the following:

**2.1** Diagnosis of moderately to severely active RA

**AND**

**2.2** Patient is NOT receiving Xeljanz/Xeljanz XR in combination with either of the following:

Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Rinvoq (upadacitinib), Olumiant (baricitinib)]

Potent immunosuppressant (e.g., azathioprine or cyclosporine)

**AND**

**2.3** Patient is currently on Xeljanz/Xeljanz XR therapy as confirmed by claims history or submission of medical records

**AND**

**2.4** Prescribed by or in consultation with a rheumatologist

|       |                                          |
|-------|------------------------------------------|
| Notes | *See Table 1 in Background for PDL Links |
|-------|------------------------------------------|

|                                       |                           |
|---------------------------------------|---------------------------|
| Product Name:Xeljanz tabs, Xeljanz XR |                           |
| Diagnosis                             | Psoriatic Arthritis (PsA) |
| Approval Length                       | 12 month(s)               |
| Therapy Stage                         | Initial Authorization     |
| Guideline Type                        | Prior Authorization       |

**Approval Criteria**

**1 - ALL of the following:**

**1.1** Diagnosis of active psoriatic arthritis

**AND**

**1.2 ONE of the following:**

**1.2.1** Failure to a 3 month trial of methotrexate at the maximally indicated dose as confirmed by claims history or submission of medical records

**OR**

**1.2.2** History of intolerance or contraindication to methotrexate (please specify intolerance or contraindication)

**OR**

**1.2.3** Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of psoriatic arthritis as confirmed by claims history or submission of medical records [e.g., Enbrel (etanercept), Cimzia (certolizumab), adalimumab, Simponi (golimumab), Orencia (abatacept), ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

**AND**

**1.3 ONE of the following:**

**1.3.1** BOTH of the following:

**1.3.1.1** One of the following:

**1.3.1.1.1** Failure to TWO of the following as confirmed by claims history or submission of medical records:

One of the preferred adalimumab products\*

Enbrel (etanercept)

One of the preferred ustekinumab products\*

**OR**

**1.3.1.1.2** History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication):

One of the preferred adalimumab products\*

Enbrel (etanercept)

One of the preferred ustekinumab products\*

**AND**

**1.3.1.2** One of the following:

**1.3.1.2.1** Failure to Cosentyx (secukinumab) as confirmed by claims history or submission of medical records

**OR**

**1.3.1.2.2** History of intolerance or contraindication to Cosentyx (secukinumab) (please specify intolerance or contraindication)

**OR**

**1.3.2** Patient has a documented needle-phobia to the degree that the patient has previously

refused any injectable therapy or medical procedure (refer to DSM-V-TR 300.29 for specific phobia diagnostic criteria)

**AND**

**1.4** Patient is NOT receiving Xeljanz/Xeljanz XR in combination with either of the following:

Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Rinvoq (upadacitinib), Olumiant (baricitinib), Otezla (apremilast)]

Potent immunosuppressant (e.g., azathioprine or cyclosporine)

**AND**

**1.5** Prescribed by or in consultation with ONE of the following:

Rheumatologist

Dermatologist

**OR**

**2** - ALL of the following:

**2.1** Patient is currently on Xeljanz/Xeljanz XR therapy as confirmed by claims history or submission of medical records

**AND**

**2.2** Diagnosis of active psoriatic arthritis

**AND**

**2.3** Patient is NOT receiving Xeljanz/Xeljanz XR in combination with either of the following:

Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Rinvoq (upadacitinib), Olumiant (baricitinib), Otezla (apremilast)]

Potent immunosuppressant (e.g., azathioprine or cyclosporine)

**AND**

**2.4** Prescribed by or in consultation with ONE of the following:

Rheumatologist

Dermatologist

|       |                                          |
|-------|------------------------------------------|
| Notes | *See Table 1 in Background for PDL Links |
|-------|------------------------------------------|

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                         |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|
| Product Name: Xeljanz tabs, Xeljanz XR                                                                                                                                                                                                                                                                                                                                                                                                                                          |                         |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Ulcerative Colitis (UC) |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 12 month(s)             |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Initial Authorization   |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Prior Authorization     |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - ALL of the following:</p> <p><b>1.1</b> Diagnosis of moderately to severely active ulcerative colitis (UC)</p> <p><b>AND</b></p> <p><b>1.2</b> ONE of the following:</p> <p><b>1.2.1</b> Patient has had prior or concurrent inadequate response to a therapeutic course of oral corticosteroids and/or immunosuppressants (e.g., azathioprine, 6-mercaptopurine) as confirmed by claims history or submitted medical records</p> |                         |

**OR**

**1.2.2** Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of ulcerative colitis as confirmed by claims history or submission of medical records [e.g., Simponi (golimumab), ustekinumab, Rinvoq (upadacitinib)]

**AND**

**1.3** ONE of the following:

**1.3.1** Failure to ONE of the following as confirmed by claims history or submission of medical records:

One of the preferred adalimumab products\*

One of the preferred ustekinumab products\*

**OR**

**1.3.2** History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

One of the preferred adalimumab products\*

One of the preferred ustekinumab products\*

**OR**

**1.3.3** Patient has a documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-V-TR 300.29 for specific phobia diagnostic criteria)

**AND**

**1.4** Patient is NOT receiving Xeljanz/Xeljanz XR in combination with either of the following:

Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Rinvoq (upadacitinib), Olumiant (baricitinib), ustekinumab, Skyrizi (risankizumab)]

Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

**AND**

**1.5** Prescribed by or in consultation with a gastroenterologist

**OR**

**2** - ALL of the following:

**2.1** Patient is currently on Xeljanz/Xeljanz XR therapy as confirmed by claims history or submission of medical records

**AND**

**2.2** Diagnosis of moderately to severely active UC

**AND**

**2.3** Patient is NOT receiving Xeljanz/Xeljanz XR in combination with either of the following:

Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Rinvoq (upadacitinib), Olumiant (baricitinib), ustekinumab, Skyrizi (risankizumab)]

Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

**AND**

**2.4** Prescribed by or in consultation with a gastroenterologist

|       |                                          |
|-------|------------------------------------------|
| Notes | *See Table 1 in Background for PDL Links |
|-------|------------------------------------------|



|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                        |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|
| Product Name:Xeljanz tabs, Xeljanz XR                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                        |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Ankylosing Spondylitis |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 12 month(s)            |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Initial Authorization  |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Prior Authorization    |
| <p><b>Approval Criteria</b></p> <p><b>1 - ALL of the following:</b></p> <p><b>1.1</b> Diagnosis of active ankylosing spondylitis</p> <p style="text-align: center;"><b>AND</b></p> <p><b>1.2</b> One of the following:</p> <p><b>1.2.1</b> Failure to two NSAIDs (e.g., ibuprofen, naproxen) at maximally indicated doses, each used for at least 4 weeks, as confirmed by claims history or submission of medical records</p> <p style="text-align: center;"><b>OR</b></p> <p><b>1.2.2</b> History of intolerance or contraindication to two NSAIDs (e.g., ibuprofen, naproxen) (please specify intolerance or contraindication)</p> <p style="text-align: center;"><b>OR</b></p> <p><b>1.2.3</b> Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of ankylosing spondylitis as confirmed by claims history or submission of medical records [e.g., Enbrel (etanercept), Cimzia (certolizumab), adalimumab, Simponi (golimumab), Rinvoq (upadacitinib)]</p> <p style="text-align: center;"><b>AND</b></p> <p><b>1.3 ONE of the following:</b></p> <p><b>1.3.1</b> BOTH of the following:</p> |                        |

**1.3.1.1** One of the following:

**1.3.1.1.1** Failure to BOTH of the following as confirmed by claims history or submission of medical records:

One of the preferred adalimumab products\*

Enbrel (etanercept)

**OR**

**1.3.1.1.2** History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

One of the preferred adalimumab products\*

Enbrel (etanercept)

**AND**

**1.3.1.2** ONE of the following:

**1.3.1.2.1** Failure to Cosentyx (secukinumab) as confirmed by claims history or submission of medical records

**OR**

**1.3.1.2.2** History of intolerance or contraindication to Cosentyx (secukinumab) (please specify intolerance or contraindication)

**OR**

**1.3.2** Patient has a documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-V-TR 300.29 for specific phobia diagnostic criteria)

**AND**

**1.4** Patient is NOT receiving Xeljanz/Xeljanz XR in combination with either of the following:

Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Rinvoq (upadacitinib), Olumiant (baricitinib)]

Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

**AND**

**1.5** Prescribed by or in consultation with a rheumatologist

**OR**

**2** - ALL of the following:

**2.1** Patient is currently on Xeljanz/Xeljanz XR therapy as confirmed by claims history or submission of medical records

**AND**

**2.2** Diagnosis of active ankylosing spondylitis

**AND**

**2.3** Patient is NOT receiving Xeljanz/Xeljanz XR in combination with either of the following:

Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Rinvoq (upadacitinib), Olumiant (baricitinib)]

Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

**AND**

**2.4** Prescribed by or in consultation with a rheumatologist

Notes

\*See Table 1 in Background for PDL Links

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                       |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------|
| Product Name:Xeljanz tabs, Xeljanz XR                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                       |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Rheumatoid Arthritis (RA), Psoriatic Arthritis (PsA), Ulcerative Colitis (UC), Ankylosing Spondylitis |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 12 month(s)                                                                                           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Reauthorization                                                                                       |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Prior Authorization                                                                                   |
| <p><b>Approval Criteria</b></p> <p>1 - Documentation of positive clinical response to Xeljanz/Xeljanz XR therapy</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Patient is NOT receiving Xeljanz/Xeljanz XR in combination with either of the following:</p> <p style="padding-left: 40px;">Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Rinvoq (upadacitinib), Olumiant (baricitinib), Otezla (apremilast)]*</p> <p style="padding-left: 40px;">Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)*</p> |                                                                                                       |
| Notes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | * Examples of drug(s) may not be applicable based on the requested indication.                        |

|                                     |                                                            |
|-------------------------------------|------------------------------------------------------------|
| Product Name:Xeljanz tabs/oral soln |                                                            |
| Diagnosis                           | Polyarticular Course Juvenile Idiopathic Arthritis (pcJIA) |
| Approval Length                     | 12 month(s)                                                |
| Therapy Stage                       | Initial Authorization                                      |
| Guideline Type                      | Prior Authorization                                        |
| <p><b>Approval Criteria</b></p>     |                                                            |

**1 - ALL of the following:**

**1.1** Diagnosis of active polyarticular course juvenile idiopathic arthritis

**AND**

**1.2** ONE of the following:

**1.2.1** Failure to ALL of the following as confirmed by claims history or submission of medical records:

One of the preferred adalimumab products\*

Enbrel (etanercept)

Tyenne (tocilizumab-aazg)

**OR**

**1.2.2** History of intolerance or contraindication to ALL of the following (please specific intolerance or contraindication):

One of the preferred adalimumab products\*

Enbrel (etanercept)

Tyenne (tocilizumab-aazg)

**OR**

**1.2.3** Patient has a documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-V-TR 300.29 for specific phobia diagnostic criteria)

**AND**

**1.3** Patient is NOT receiving Xeljanz/Xeljanz oral solution in combination with either of the following:

Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Olumiant (baricitinib), Rinvoq (upadacitinib)]

Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

**AND**

**1.4** Prescribed by or in consultation with a rheumatologist

**OR**

**2** - ALL of the following:

**2.1** Patient is currently on Xeljanz/Xeljanz Oral Solution as confirmed by claims history or submission of medical records

**AND**

**2.2** Diagnosis of active polyarticular course juvenile idiopathic arthritis

**AND**

**2.3** Patient is NOT receiving Xeljanz/Xeljanz Oral Solution in combination with either of the following:

Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Olumiant (baricitinib), Rinvoq (upadacitinib)]

Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

**AND**

**2.4** Prescribed by or in consultation with a rheumatologist

|       |                                          |
|-------|------------------------------------------|
| Notes | *See Table 1 in Background for PDL Links |
|-------|------------------------------------------|

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                            |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------|
| Product Name:Xeljanz tabs/oral soln                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                            |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Polyarticular Course Juvenile Idiopathic Arthritis (pcJIA) |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 12 month(s)                                                |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Reauthorization                                            |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Prior Authorization                                        |
| <p><b>Approval Criteria</b></p> <p>1 - Documentation of positive clinical response to Xeljanz or Xeljanz oral solution therapy</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Patient is NOT receiving Xeljanz or Xeljanz oral solution in combination with either of the following:</p> <p style="padding-left: 40px;">Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Olumiant (baricitinib), Rinvoq (upadacitinib)]</p> <p style="padding-left: 40px;">Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)</p> |                                                            |

## 2 . Background

| Benefit/Coverage/Program Information                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p><b>Table 1. PDL Links</b></p> <p>CO: <a href="https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html</a></p> <p>HI: <a href="https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html</a></p> <p>MD: <a href="https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-cp-pharmacy.html</a></p> |

NM: <https://www.uhcprovider.com/en/health-plans-by-state/new-mexico-health-plans/nm-comm-plan-home/nm-cp-pharmacy.html>

NJ: <https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html>

NY: <https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html>

PA CHIP: <https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP>

RI: <https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html>

### 3 . Revision History

| Date     | Notes                                                                                                                                                             |
|----------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 3/5/2025 | Updated formularies. Added ustekinumab as a step therapy option in PsA and UC. Replaced Stelara with ustekinumab throughout. Added NM to PDL links in background. |



Xenazine



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-135293                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Guideline Name</b> | Xenazine                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Formulary</b>      | Medicaid - Community & State Colorado (ACUCO, ACUCOC)<br>Medicaid - Community & State Hawaii (ACUHI, ACUHIEC)<br>Medicaid - Community & State Maryland (ACUMD)<br>Medicaid - Community & State New Jersey (PSI2300)<br>Medicaid - Community & State New York EPP (ACUNYEPP)<br>Medicaid - Community & State New York (ACUNY, ACUNYM)<br>Medicaid - Community & State Pennsylvania CHIP (ACUPAC)<br>Medicaid - Community & State Rhode Island (ACURI) |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 1/1/2024 |
|-----------------|----------|

## 1 . Criteria

|                                                     |                                             |
|-----------------------------------------------------|---------------------------------------------|
| Product Name: Brand Xenazine, generic tetrabenazine |                                             |
| Diagnosis                                           | Chorea associated with Huntington's Disease |
| Approval Length                                     | 12 month(s)                                 |
| Guideline Type                                      | Prior Authorization                         |
|                                                     |                                             |

**Approval Criteria**

1 - Diagnosis of chorea in patients with Huntington's disease

Product Name: Brand Xenazine, generic tetrabenazine

|           |                                |
|-----------|--------------------------------|
| Diagnosis | Tardive Dyskinesia (Off-Label) |
|-----------|--------------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

1 - Diagnosis of tardive dyskinesia

**AND**

2 - ONE of the following:

**2.1** Patient has persistent symptoms of tardive dyskinesia despite a trial of dose reduction, tapering, or discontinuation of the offending medication

**OR**

**2.2** Patient is not a candidate for a trial of dose reduction, tapering, or discontinuation of the offending medication

**AND**

3 - Prescribed by or in consultation with ONE of the following:

Neurologist

Psychiatrist

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                 |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|
| Product Name: Brand Xenazine, generic tetrabenazine                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                 |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Tourette's Syndrome (Off-Label) |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 12 month(s)                     |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Initial Authorization           |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Prior Authorization             |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Patient has tics associated with Tourette's syndrome</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - ONE of the following:</p> <p><b>2.1</b> Failure of haloperidol confirmed by claims history or submitted medical records</p> <p style="text-align: center;"><b>OR</b></p> <p><b>2.2</b> History of intolerance or contraindication to haloperidol (please specify intolerance or contraindication)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Prescribed by or in consultation with ONE of the following:</p> <p style="padding-left: 40px;">Neurologist</p> <p style="padding-left: 40px;">Psychiatrist</p> |                                 |

|                                                     |                                                                 |
|-----------------------------------------------------|-----------------------------------------------------------------|
| Product Name: Brand Xenazine, generic tetrabenazine |                                                                 |
| Diagnosis                                           | Tardive Dyskinesia (Off-Label), Tourette's Syndrome (Off-Label) |
| Approval Length                                     | 12 month(s)                                                     |
| Therapy Stage                                       | Reauthorization                                                 |

|                                                                                               |                     |
|-----------------------------------------------------------------------------------------------|---------------------|
| Guideline Type                                                                                | Prior Authorization |
| <b>Approval Criteria</b><br><b>1</b> - Documentation of positive clinical response to therapy |                     |

## 2 . Revision History

| Date       | Notes                    |
|------------|--------------------------|
| 10/23/2023 | Removed RMH CO Formulary |

Xenleta



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-228227                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Guideline Name</b> | Xenleta                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Formulary</b>      | Medicaid - Community & State Colorado (ACUCO, ACUCOC)<br>Medicaid - Community & State Hawaii (ACUHI, ACUHIEC)<br>Medicaid - Community & State Indiana (ACUIN)<br>Medicaid - Community & State Maryland (ACUMD)<br>Medicaid - Community & State Michigan (ACUMI)<br>Medicaid - Community & State Nebraska (ACUNE)<br>Medicaid - Community & State New Jersey (PSI2300)<br>Medicaid - Community & State New Mexico (ACUNM)<br>Medicaid - Community & State New York (ACUNY, ACUNYM)<br>Medicaid - Community & State New York EPP (ACUNYEPP)<br>Medicaid - Community & State Pennsylvania (ACUPA)<br>Medicaid - Community & State Pennsylvania CHIP (ACUPAC)<br>Medicaid - Community & State Rhode Island (ACURI)<br>Medicaid - Community & State Virginia (ACUVA, ACUVAC, ACUVAEC) |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 5/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                      |                                        |
|----------------------|----------------------------------------|
| Product Name:Xenleta |                                        |
| Diagnosis            | Community-acquired bacterial pneumonia |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                     |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 7 Day(s)            |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1 - One of the following:</b></p> <p><b>1.1</b> For continuation of therapy upon hospital discharge</p> <p style="text-align: center;"><b>OR</b></p> <p><b>1.2</b> As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication</p> <p style="text-align: center;"><b>OR</b></p> <p><b>1.3</b> All of the following:</p> <p><b>1.3.1</b> Diagnosis of community-acquired bacterial pneumonia (CABP)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>1.3.2</b> Infection caused by an organism that is confirmed to be or likely to be susceptible to treatment with Xenleta</p> <p style="text-align: center;"><b>AND</b></p> <p><b>1.3.3</b> One of the following:</p> <p><b>1.3.3.1</b> Failure to three of the following antibiotics or antibiotic regimens confirmed by claims history or submitted medical records:</p> <p>Amoxicillin</p> <p>A macrolide</p> |                     |

Doxycycline

A fluoroquinolone

Combination therapy with amoxicillin/clavulanate or cephalosporin AND a macrolide or doxycycline

**OR**

**1.3.3.2** History of contraindication or intolerance to all of the following antibiotics or antibiotic regimens (please specify intolerance or contraindication):

Amoxicillin

A macrolide

Doxycycline

A fluoroquinolone

Combination therapy with amoxicillin/clavulanate or cephalosporin AND a macrolide or doxycycline

|                                                                                                                                                                |                                                                                    |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------|
| Product Name:Xenleta                                                                                                                                           |                                                                                    |
| Diagnosis                                                                                                                                                      | Off-Label Uses                                                                     |
| Approval Length                                                                                                                                                | Based on provider and IDSA recommended treatment durations, not to exceed 6 months |
| Guideline Type                                                                                                                                                 | Prior Authorization                                                                |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - One of the following:</p> <p><b>1.1</b> For continuation of therapy upon hospital discharge</p> <p><b>OR</b></p> |                                                                                    |

**1.2** As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication

**OR**

**1.3** The drug has been recognized for treatment of the indication by the Infectious Diseases Society of America (IDSA)

## **2 . Revision History**

| Date      | Notes               |
|-----------|---------------------|
| 3/27/2025 | Updated formularies |



Xermelo



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-356196                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Guideline Name</b> | Xermelo                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Formulary</b>      | Medicaid - Community & State Colorado (ACUCO, ACUCOC)<br>Medicaid - Community & State Hawaii (ACUHI, ACUHIEC)<br>Medicaid - Community & State Maryland (ACUMD)<br>Medicaid - Community & State New Jersey (PSI2300)<br>Medicaid - Community & State New York (ACUNY, ACUNYM)<br>Medicaid - Community & State New York EPP (ACUNYEPP)<br>Medicaid - Community & State Pennsylvania CHIP (ACUPAC)<br>Medicaid - Community & State Rhode Island (ACURI)<br>Medicaid - Community & State Indiana (ACUIN)<br>Medicaid - Community & State Nebraska (ACUNE)<br>Medicaid - Community & State New Mexico (ACUNM)<br>Medicaid - Community & State Pennsylvania (ACUPA)<br>Medicaid - Community & State Virginia (ACUVA, ACUVAC, ACUVAEC)<br>Medicaid - Community & State Washington (ACUWA, ACUWAAHE, ACUWAC) |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 9/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                      |
|----------------------|
| Product Name:Xermelo |
|----------------------|

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                             |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Carcinoid Syndrome Diarrhea |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 12 month(s)                 |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Initial Authorization       |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Prior Authorization         |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of carcinoid syndrome diarrhea</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Diarrhea is inadequately controlled with somatostatin analog therapy (e.g., octreotide, Sandostatin LAR, Somatuline Depot, Lanreotide), as confirmed by claims history or submission of medical records</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Used in combination with somatostatin analog therapy (e.g., octreotide, Sandostatin LAR, Somatuline Depot, Lanreotide)</p> |                             |

|                                                                                                          |                             |
|----------------------------------------------------------------------------------------------------------|-----------------------------|
| Product Name:Xermelo                                                                                     |                             |
| Diagnosis                                                                                                | Carcinoid Syndrome Diarrhea |
| Approval Length                                                                                          | 12 month(s)                 |
| Therapy Stage                                                                                            | Reauthorization             |
| Guideline Type                                                                                           | Prior Authorization         |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of positive clinical response to Xermelo</p> |                             |

## 2 . Revision History

UnitedHealthcare Community Plan of New Jersey – Clinical Pharmacy Guidelines

| Date     | Notes                                                  |
|----------|--------------------------------------------------------|
| 8/1/2025 | Combined formularies. No changes to clinical criteria. |

Xifaxan



## Prior Authorization Guideline

|                       |                                                   |
|-----------------------|---------------------------------------------------|
| <b>Guideline ID</b>   | GL-424189                                         |
| <b>Guideline Name</b> | Xifaxan                                           |
| <b>Formulary</b>      | Medicaid - Community & State New Jersey (PSI2300) |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 11/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                                                                                                    |                             |
|----------------------------------------------------------------------------------------------------|-----------------------------|
| Product Name:Xifaxan 550mg                                                                         |                             |
| Diagnosis                                                                                          | Hepatic Encephalopathy (HE) |
| Approval Length                                                                                    | 12 month(s)                 |
| Therapy Stage                                                                                      | Initial Authorization       |
| Guideline Type                                                                                     | Prior Authorization         |
| <b>Approval Criteria</b><br><br>1 - Used for prophylaxis of hepatic encephalopathy (HE) recurrence |                             |

## AND

**2 - ONE** of the following:

**2.1 BOTH** of the following:

Used as add-on therapy to lactulose, confirmed by claims history or submitted medical records

Patient is unable to achieve an optimal clinical response with lactulose monotherapy, confirmed by claims history or submitted medical records

## OR

**2.2** History of contraindication or intolerance to lactulose (please specify intolerance or contraindication)

|       |                                                                                                                                                                   |
|-------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Notes | Due to the manufacturer of Xifaxan no longer participating in the Medicaid Drug Rebate Program, all other strengths and indications of Xifaxan are not coverable. |
|-------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                                                                                                           |                                                                                                                                                                   |
|-----------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Product Name:Xifaxan 550mg                                                                                |                                                                                                                                                                   |
| Diagnosis                                                                                                 | Hepatic Encephalopathy (HE)                                                                                                                                       |
| Approval Length                                                                                           | 12 month(s)                                                                                                                                                       |
| Therapy Stage                                                                                             | Reauthorization                                                                                                                                                   |
| Guideline Type                                                                                            | Prior Authorization                                                                                                                                               |
| <b>Approval Criteria</b><br><br><b>1 - Documentation of positive clinical response to Xifaxan therapy</b> |                                                                                                                                                                   |
| Notes                                                                                                     | Due to the manufacturer of Xifaxan no longer participating in the Medicaid Drug Rebate Program, all other strengths and indications of Xifaxan are not coverable. |

## 2 . Revision History

UnitedHealthcare Community Plan of New Jersey – Clinical Pharmacy Guidelines

| Date       | Notes                                                                   |
|------------|-------------------------------------------------------------------------|
| 10/16/2025 | NJ standalone created. Removed all indications except HE. Removed 200mg |

Xolair



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-273195                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Guideline Name</b> | Xolair                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Formulary</b>      | Medicaid - Community & State Colorado (ACUCO, ACUCOC)<br>Medicaid - Community & State Hawaii (ACUHI, ACUHIEC)<br>Medicaid - Community & State Maryland (ACUMD)<br>Medicaid - Community & State New Jersey (PSI2300)<br>Medicaid - Community & State New York (ACUNY, ACUNYM)<br>Medicaid - Community & State New York EPP (ACUNYEPP)<br>Medicaid - Community & State Pennsylvania CHIP (ACUPAC)<br>Medicaid - Community & State Rhode Island (ACURI)<br>Medicaid - Community & State New Mexico (ACUNM) |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 7/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                     |                                                                 |
|---------------------|-----------------------------------------------------------------|
| Product Name:Xolair |                                                                 |
| Diagnosis           | Asthma                                                          |
| Approval Length     | 12 month(s)                                                     |
| Therapy Stage       | Initial Authorization - Transitioning from UHC medical benefits |
| Guideline Type      | Prior Authorization                                             |

**Approval Criteria**

**1** - Patient has been established on therapy with Xolair for moderate to severe persistent asthma under an active UnitedHealthcare medical benefit prior authorization

**AND**

**2** - Documentation of positive clinical response to Xolair therapy as demonstrated by at least ONE of the following

**2.1** Reduction in the frequency of exacerbations

**OR**

**2.2** Decreased utilization of rescue medications

**OR**

**2.3** Increase in percent predicted forced expiratory volume (FEV1) from pretreatment baseline

**OR**

**2.4** Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.)

**AND**

**3** - Xolair is being used in combination with an inhaled corticosteroid (ICS)-containing maintenance medication [e.g., Advair/AirDuo (fluticasone/salmeterol), Breo Ellipta (fluticasone furoate/vilanterol), Symbicort (budesonide/ formoterol), Trelegy Ellipta (fluticasone furoate/umeclidinium/vilanterol)]

**AND**



**4** - Patient is not receiving Xolair in combination with any of the following:

Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]

Anti-interleukin 5 therapy [e.g., Nucala (mepolizumab), Cinqair (reslizumab), Fasenra (benralizumab)]

Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

| Product Name:Xolair                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                     |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------|
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Asthma                                                              |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 12 month(s)                                                         |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Initial Authorization - Not transitioning from UHC medical benefits |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Prior Authorization                                                 |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of moderate or severe asthma</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Classification of asthma as uncontrolled or inadequately controlled as defined by at least ONE of the following:</p> <p><b>2.1</b> Poor symptom control [e.g., Asthma Control Questionnaire (ACQ) score consistently greater than 1.5 or Asthma Control Test (ACT) score consistently less than 20]</p> <p style="text-align: center;"><b>OR</b></p> <p><b>2.2</b> Two or more bursts of systemic corticosteroids for at least 3 days each in the previous 12 months</p> <p style="text-align: center;"><b>OR</b></p> |                                                                     |

**2.3** Asthma-related emergency treatment (e.g., emergency room visit, hospital admission, or unscheduled physician's office visit for nebulizer or other urgent treatment)

**OR**

**2.4** Airflow limitation [e.g., after appropriate bronchodilator withhold forced expiratory volume in 1 second (FEV1) less than 80% predicted (in the face of reduced FEV1-forced vital capacity [FVC] defined as less than the lower limit of normal)]

**OR**

**2.5** Patient is currently dependent on oral corticosteroids for the treatment of asthma

**AND**

**3** - Submission of medical records (e.g., chart notes, laboratory values, etc.) documenting a baseline (pre-omalizumab treatment) serum total IgE (immunoglobulin E) level greater than or equal to 30 IU/mL (international units/milliliter) and less than or equal to 1300 IU/mL

**AND**

**4** - Positive skin test or in vitro reactivity to a perennial aeroallergen

**AND**

**5** - Used in combination with ONE of the following:

**5.1** ONE maximally-dosed (appropriately adjusted for age) combination inhaled corticosteroid (ICS)-long-acting beta2-agonist (LABA) product [e.g., fluticasone propionate-salmeterol (AirDuo, Advair), budesonide-formoterol (Symbicort)]

**OR**

**5.2** Combination therapy including BOTH of the following:

**5.2.1** One maximally-dosed (appropriately adjusted for age) ICS (inhaled corticosteroid)

product [e.g., ciclesonide (Alvesco), mometasone furoate (Asmanex), beclomethasone dipropionate (QVAR)]

**AND**

**5.2.2** One additional asthma controller medication [e.g., LABA - olodaterol (Striverdi) or indacaterol (Arcapta); leukotriene receptor antagonist - montelukast (Singulair); theophylline]

**AND**

**6** - Patient is not receiving Xolair in combination with any of the following:

Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]

Anti-interleukin 5 therapy [e.g., Nucala (mepolizumab), Cinqair (reslizumab), Fasenra (benralizumab)]

Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

**AND**

**7** - Prescribed by ONE of the following:

Allergist

Immunologist

Pulmonologist

|                     |                     |
|---------------------|---------------------|
| Product Name:Xolair |                     |
| Diagnosis           | Asthma              |
| Approval Length     | 12 month(s)         |
| Therapy Stage       | Reauthorization     |
| Guideline Type      | Prior Authorization |
|                     |                     |

## Approval Criteria

**1** - Documentation of positive clinical response as demonstrated by at least ONE of the following:

Reduction in frequency of exacerbations

Decreased utilization of rescue medications

Increase in percent predicted FEV1 (forced expiratory volume in 1 second) from pretreatment baseline

Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing)

**AND**

**2** - Used in combination with an ICS (inhaled corticosteroid)-containing maintenance medication [e.g., Advair/AirDuo (fluticasone/salmeterol), Breo Ellipta (fluticasone furoate/vilanterol), Symbicort (budesonide/ formoterol), Trelegy Ellipta (fluticasone furoate/umeclidinium/vilanterol)]

**AND**

**3** - Patient is not receiving Xolair in combination with any of the following:

Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]

Anti-interleukin 5 therapy [e.g., Nucala (mepolizumab), Cinqair (reslizumab), Fasenra (benralizumab)]

Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

|                     |                                                                 |
|---------------------|-----------------------------------------------------------------|
| Product Name:Xolair |                                                                 |
| Diagnosis           | Chronic Urticaria                                               |
| Approval Length     | 12 month(s)                                                     |
| Therapy Stage       | Initial Authorization - Transitioning from UHC medical benefits |
| Guideline Type      | Prior Authorization                                             |

**Approval Criteria**

**1** - Patient has been established on therapy with Xolair for chronic urticaria under an active UnitedHealthcare medical benefit prior authorization

**AND**

**2** - Documentation of positive clinical response to Xolair therapy (e.g., reduction in exacerbations, itch severity, hives)

**AND**

**3** - Patient is not receiving Xolair in combination with any of the following:

Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]

Anti-interleukin 5 therapy [e.g., Nucala (mepolizumab), Cinqair (reslizumab), Fasenra (benralizumab)]

Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

|                                                                                                    |                                                                     |
|----------------------------------------------------------------------------------------------------|---------------------------------------------------------------------|
| Product Name:Xolair                                                                                |                                                                     |
| Diagnosis                                                                                          | Chronic Urticaria                                                   |
| Approval Length                                                                                    | 12 month(s)                                                         |
| Therapy Stage                                                                                      | Initial Authorization - Not transitioning from UHC medical benefits |
| Guideline Type                                                                                     | Prior Authorization                                                 |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of chronic urticaria</p> <p><b>AND</b></p> |                                                                     |

**2 - ONE of the following:**

**2.1** Patient remains symptomatic despite at least a 2-week trial and failure of two H1-antihistamines [e.g., Allegra (fexofenadine), Benadryl (diphenhydramine), Claritin (loratadine)]\* (confirmed by claims history or submitted medical records)

**OR**

**2.2** Patient remains symptomatic despite at least a 2-week trial and failure of BOTH of the following taken in combination (confirmed by claims history or submitted medical records):

**2.2.1** Second generation H1-antihistamine [e.g., Allegra (fexofenadine), Claritin (loratadine), Zyrtec (cetirizine)]

**AND**

**2.2.2** ONE of the following:

Different second generation H1-antihistamine [e.g., Allegra (fexofenadine), Claritin (loratadine), Zyrtec (cetirizine)]

First generation H1-antihistamine [e.g., Benadryl (diphenhydramine), Chlor-Trimeton (chlorpheniramine), Vistaril (hydroxyzine)]\*

H2-antihistamine [e.g., Pepcid (famotidine), Tagamet HB (cimetidine), Zantac (ranitidine)]

Leukotriene modifier [e.g., Singulair (montelukast)]

**OR**

**2.3** History of contraindication or intolerance to ONE of the following (please specify contraindication or intolerance):

**2.3.1** Two H1-antihistamines [e.g., Allegra (fexofenadine), Benadryl (diphenhydramine), Claritin (loratadine)]\*

**OR**

**2.3.2** BOTH of the following taken in combination:

**2.3.2.1** Second generation H1-antihistamine [e.g., Allegra (fexofenadine), Claritin (loratadine), Zyrtec (cetirizine)]

**AND**

**2.3.2.2** ONE of the following:

Different second generation H1-antihistamine [e.g., Allegra (fexofenadine), Claritin (loratadine), Zyrtec (cetirizine)]

First generation H1-antihistamine [e.g., Benadryl (diphenhydramine), Chlor-Trimeton (chlorpheniramine), Vistaril (hydroxyzine)]\*

H2-antihistamine [e.g., Pepcid (famotidine), Tagamet HB (cimetidine), Zantac (ranitidine)]

Leukotriene modifier [e.g., Singulair (montelukast)]

**AND**

**3** - Patient is not receiving Xolair in combination with any of the following:

Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]

Anti-interleukin 5 therapy [e.g., Nucala (mepolizumab), Cinqair (reslizumab), Fasenra (benralizumab)]

Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

**AND**

**4** - Prescribed by one of the following:

Allergist

Dermatologist

Immunologist

Notes

\*Patients 65 years of age and older in whom first generation H1-antihistamines are considered high risk medications to be avoided (e.g., Be

|  |                                                                                                |
|--|------------------------------------------------------------------------------------------------|
|  | ers criteria, HEDIS) should be directed to try alternatives that are not considered high risk. |
|--|------------------------------------------------------------------------------------------------|

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                     |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Xolair                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                     |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Chronic Urticaria   |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 12 month(s)         |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p>1 - Documentation of positive clinical response (e.g., reduction in exacerbations, itch severity, hives)</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Patient is not receiving Xolair in combination with any of the following:</p> <p style="padding-left: 40px;">Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]</p> <p style="padding-left: 40px;">Anti-interleukin 5 therapy [e.g., Nucala (mepolizumab), Cinqair (reslizumab), Fasenra (benralizumab)]</p> <p style="padding-left: 40px;">Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]</p> |                     |

|                                 |                                                                 |
|---------------------------------|-----------------------------------------------------------------|
| Product Name:Xolair             |                                                                 |
| Diagnosis                       | Nasal Polyps                                                    |
| Approval Length                 | 12 month(s)                                                     |
| Therapy Stage                   | Initial Authorization - Transitioning from UHC medical benefits |
| Guideline Type                  | Prior Authorization                                             |
| <p><b>Approval Criteria</b></p> |                                                                 |



**1** - Patient has been established on therapy with Xolair for nasal polyps under an active UnitedHealthcare medical benefit prior authorization

**AND**

**2** - Documentation of positive clinical response to Xolair therapy

**AND**

**3** - Patient will continue to receive Xolair as add-on maintenance therapy in combination with intranasal corticosteroids (e.g., fluticasone, mometasone, triamcinolone)

**AND**

**4** - Patient is not receiving Xolair in combination with any of the following:

Anti-interleukin 5 therapy [e.g., Cinqair (reslizumab), Fasenra (benralizumab), Nucala (mepolizumab)]

Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]

Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

|                                                                      |                                                                     |
|----------------------------------------------------------------------|---------------------------------------------------------------------|
| Product Name:Xolair                                                  |                                                                     |
| Diagnosis                                                            | Nasal Polyps                                                        |
| Approval Length                                                      | 12 month(s)                                                         |
| Therapy Stage                                                        | Initial Authorization - Not transitioning from UHC medical benefits |
| Guideline Type                                                       | Prior Authorization                                                 |
| <b>Approval Criteria</b><br><br><b>1</b> - Diagnosis of nasal polyps |                                                                     |

**AND**

**2** - TWO or more of the following symptoms for longer than 12 weeks duration:

Nasal mucopurulent discharge

Nasal obstruction, blockage, or congestion

Facial pain, pressure, and/or fullness

Reduction or loss of sense of smell

**AND**

**3** - ONE of the following findings using nasal endoscopy and/or sinus computed tomography (CT):

Purulent mucus or edema in the middle meatus or ethmoid regions

Polyps in the nasal cavity or the middle meatus

Radiographic imaging demonstrating mucosal thickening or partial or complete opacification of paranasal sinuses

**AND**

**4** - ONE of the following:

**4.1** Patient has required prior sinus surgery

**OR**

**4.2** Patient has required systemic corticosteroids (e.g., prednisone, methylprednisolone) for nasal polyps in the previous 2 years

**OR**

**4.3** Patient has been unable to obtain symptom relief after trial of BOTH of the following confirmed by claims history or submitted medical records:

Intranasal corticosteroids (e.g., fluticasone, mometasone, triamcinolone)

One other therapy used in management of nasal polyps [i.e., nasal saline irrigations, antileukotriene agents (e.g., montelukast, zafirlukast, zileuton)]

**AND**

**5** - Patient will receive Xolair as add-on maintenance therapy in combination with intranasal corticosteroids (e.g., fluticasone, mometasone, triamcinolone)

**AND**

**6** - Patient is not receiving Xolair in combination with any of the following:

Anti-interleukin 5 therapy [e.g., Cinqair (reslizumab), Fasenra (benralizumab), Nucala (mepolizumab)]

Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]

Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

**AND**

**7** - Prescribed by one of the following:

Allergist

Immunologist

Otolaryngologist

Pulmonologist

Product Name:Xolair

Diagnosis

Nasal Polyps

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                     |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 12 month(s)         |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of positive clinical response to Xolair therapy</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Patient will continue to receive Xolair as add-on maintenance therapy in combination with intranasal corticosteroids (e.g., fluticasone, mometasone, triamcinolone)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Patient is not receiving Xolair in combination with any of the following:</p> <p style="padding-left: 40px;">Anti-interleukin 5 therapy [e.g., Cinqair (reslizumab), Fasenra (benralizumab), Nucala (mepolizumab)]</p> <p style="padding-left: 40px;">Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]</p> <p style="padding-left: 40px;">Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]</p> |                     |

|                                                                                                                                                                                                          |                                                                 |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------|
| Product Name:Xolair                                                                                                                                                                                      |                                                                 |
| Diagnosis                                                                                                                                                                                                | IgE-Mediated Food Allergy                                       |
| Approval Length                                                                                                                                                                                          | 12 month(s)                                                     |
| Therapy Stage                                                                                                                                                                                            | Initial Authorization - Transitioning from UHC medical benefits |
| Guideline Type                                                                                                                                                                                           | Prior Authorization                                             |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Patient has been established on therapy with Xolair for IgE-Mediated food allergy under an active UnitedHealthcare medical benefit prior authorization</p> |                                                                 |

**AND**

**2** - Documentation of positive clinical response to Xolair therapy (e.g., reduction in type I allergic reactions)

**AND**

**3** - Xolair will be used in conjunction with food allergen avoidance

**AND**

**4** - Patient access to epinephrine

**AND**

**5** - Patient is not receiving Xolair in combination with any of the following:

Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]

Anti-interleukin 5 therapy [e.g., Nucala (mepolizumab), Cinqair (reslizumab), Fasenra (benralizumab)]

Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

**AND**

**6** - Prescribed by an allergist or immunologist

|                     |                                                                     |
|---------------------|---------------------------------------------------------------------|
| Product Name:Xolair |                                                                     |
| Diagnosis           | IgE-Mediated Food Allergy                                           |
| Approval Length     | 12 month(s)                                                         |
| Therapy Stage       | Initial Authorization - Not transitioning from UHC medical benefits |
| Guideline Type      | Prior Authorization                                                 |

**Approval Criteria**

**1** - Diagnosis of IgE-mediated food allergy to one or more foods

**AND**

**2** - Patient is at least 1 year of age

**AND**

**3** - IgE-mediated food allergy to specific food(s) has been confirmed by both of the following:

**3.1** History of type I allergic reactions (e.g., nausea, vomiting, cramping, diarrhea, flushing, pruritus, urticaria, swelling of the lips, face or throat, wheezing, lightheadedness, syncope)

**AND**

**3.2** One of the following:

Food specific skin prick testing (SPT)

IgE antibody in vitro testing

Oral food challenge (OFC)

**AND**

**4** - Xolair will be used in conjunction with food allergen avoidance

**AND**

**5** - Patient has access to epinephrine

**AND**

**6** - Patient is not receiving Xolair in combination with any of the following:

Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]

Anti-interleukin 5 therapy [e.g., Nucala (mepolizumab), Cinqair (reslizumab), Fasenra (benralizumab)]

Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

**AND**

**7** - Prescribed by allergist or immunologist

|                                                                                                                                                                                                                                                                                                                                          |                           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Xolair                                                                                                                                                                                                                                                                                                                      |                           |
| Diagnosis                                                                                                                                                                                                                                                                                                                                | IgE-Mediated Food Allergy |
| Approval Length                                                                                                                                                                                                                                                                                                                          | 12 month(s)               |
| Therapy Stage                                                                                                                                                                                                                                                                                                                            | Reauthorization           |
| Guideline Type                                                                                                                                                                                                                                                                                                                           | Prior Authorization       |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of positive clinical response to Xolair therapy (e.g., reduction in type I allergic reactions)</p> <p><b>AND</b></p> <p><b>2</b> - Xolair will be used in conjunction with food allergen avoidance</p> <p><b>AND</b></p> <p><b>3</b> - Patient has access to epinephrine</p> |                           |

**AND**

**4** - Patient is not receiving Xolair in combination with any of the following:

Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]

Anti-interleukin 5 therapy [e.g., Nucala (mepolizumab), Cinqair (reslizumab), Fasenra (benralizumab)]

Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

**AND**

**5** - Prescribed by an allergist or immunologist

## 2 . Revision History

| Date      | Notes               |
|-----------|---------------------|
| 5/21/2025 | Updated formularies |



Xolremdi



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-424218                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Guideline Name</b> | Xolremdi                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Formulary</b>      | Medicaid - Community & State Colorado (ACUCO, ACUCOC)<br>Medicaid - Community & State Hawaii (ACUHI, ACUHIEC)<br>Medicaid - Community & State Maryland (ACUMD)<br>Medicaid - Community & State New Jersey (PSI2300)<br>Medicaid - Community & State New York (ACUNY, ACUNYM)<br>Medicaid - Community & State New York EPP (ACUNYEPP)<br>Medicaid - Community & State Pennsylvania CHIP (ACUPAC)<br>Medicaid - Community & State Rhode Island (ACURI)<br>Medicaid - Community & State Indiana (ACUIN)<br>Medicaid - Community & State Nebraska (ACUNE)<br>Medicaid - Community & State New Mexico (ACUNM)<br>Medicaid - Community & State Pennsylvania (ACUPA)<br>Medicaid - Community & State Virginia (ACUVA, ACUVAC, ACUVAEC) |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 11/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                       |                       |
|-----------------------|-----------------------|
| Product Name:Xolremdi |                       |
| Approval Length       | 12 month(s)           |
| Therapy Stage         | Initial Authorization |

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Prior Authorization |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of WHIM (warts, hypogammaglobulinemia, infections and myelokathexis) syndrome</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Patient has a genotype-confirmed mutation of chemokine (C-X-C motif) receptor 4 (CXCR4) consistent with WHIM phenotype</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Patient has an absolute neutrophil count (ANC) less than or equal to 500 cells per microliter</p> <p style="text-align: center;"><b>AND</b></p> <p><b>4</b> - Prescribed by or in consultation with ONE of the following:</p> <ul style="list-style-type: none"> <li>Allergist</li> <li>Geneticist</li> <li>Hematologist</li> <li>Immunologist</li> </ul> |                     |

|                       |                     |
|-----------------------|---------------------|
| Product Name:Xolremdi |                     |
| Approval Length       | 12 month(s)         |
| Therapy Stage         | Reauthorization     |
| Guideline Type        | Prior Authorization |

### Approval Criteria

**1** - Documentation of positive clinical response [e.g., improvement in absolute neutrophil counts (ANC), improvement in absolute lymphocyte counts (ALC), reduction in infections] to Xolremdi therapy

**AND**

**2** - Prescribed by or in consultation with ONE of the following:

Allergist

Geneticist

Hematologist

Immunologist

## 2 . Revision History

| Date       | Notes                                                  |
|------------|--------------------------------------------------------|
| 10/20/2025 | Combined formularies. No changes to clinical criteria. |

Xopenex Respules



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-231201                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Guideline Name</b> | Xopenex Respules                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Formulary</b>      | Medicaid - Community & State Colorado (ACUCO, ACUCOC)<br>Medicaid - Community & State Hawaii (ACUHI, ACUHIEC)<br>Medicaid - Community & State Maryland (ACUMD)<br>Medicaid - Community & State New Jersey (PSI2300)<br>Medicaid - Community & State New Mexico (ACUNM)<br>Medicaid - Community & State New York (ACUNY, ACUNYM)<br>Medicaid - Community & State New York EPP (ACUNYEPP)<br>Medicaid - Community & State Pennsylvania CHIP (ACUPAC)<br>Medicaid - Community & State Rhode Island (ACURI) |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 5/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                                                                                   |              |
|-----------------------------------------------------------------------------------|--------------|
| Product Name: Brand Xopenex inhalation soln, generic levalbuterol inhalation soln |              |
| Approval Length                                                                   | 12 month(s)  |
| Guideline Type                                                                    | Step Therapy |
| Approval Criteria                                                                 |              |

**1** - Failure to treatment with albuterol inhalation solution, as confirmed by claims history or submission of medical records

**OR**

**2** - History of contraindication or intolerance to albuterol inhalation solution (please specify contraindication or intolerance)

## **2 . Revision History**

| Date      | Notes                                                 |
|-----------|-------------------------------------------------------|
| 3/27/2025 | Combined formularies. No update to clinical criteria. |

Xospata



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-228195                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Guideline Name</b> | Xospata                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Formulary</b>      | Medicaid - Community & State Colorado (ACUCO, ACUCOC)<br>Medicaid - Community & State Hawaii (ACUHI, ACUHIEC)<br>Medicaid - Community & State Indiana (ACUIN)<br>Medicaid - Community & State Maryland (ACUMD)<br>Medicaid - Community & State New Jersey (PSI2300)<br>Medicaid - Community & State New Mexico (ACUNM)<br>Medicaid - Community & State New York (ACUNY, ACUNYM)<br>Medicaid - Community & State New York EPP (ACUNYEPP)<br>Medicaid - Community & State Pennsylvania CHIP (ACUPAC)<br>Medicaid - Community & State Rhode Island (ACURI) |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 5/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                      |                        |
|----------------------|------------------------|
| Product Name:Xospata |                        |
| Diagnosis            | Acute Myeloid Leukemia |
| Approval Length      | 12 month(s)            |
| Therapy Stage        | Initial Authorization  |
| Guideline Type       | Prior Authorization    |

**Approval Criteria**

**1** - Diagnosis of acute myeloid leukemia (AML)

**AND**

**2** - AML is FMS-like tyrosine kinase 3 (FLT3) mutation-positive

**AND**

**3** - ONE of the following:

Used as low-intensity treatment induction when not a candidate for intensive induction therapy

Follow-up after induction therapy with response to previous lower intensity therapy with the same regimen

Post-allogeneic hematopoietic cell transplantation and in remission

Disease is relapsed or refractory

Consolidation therapy as continuation of low-intensity regimen used for induction in patients with poor-risk AML

**Product Name:**Xospata

|           |                            |
|-----------|----------------------------|
| Diagnosis | Myeloid/Lymphoid Neoplasms |
|-----------|----------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

**1** - Diagnosis of lymphoid, myeloid, or mixed lineage neoplasms with eosinophilia

**AND**

**2** - ONE of the following:

Patient has an FMS-like tyrosine kinase 3 (FLT3) rearrangement in chronic phase

Patient has an FMS-like tyrosine kinase 3 (FLT3) rearrangement in blast phase

|                                                                                                                       |                                                    |
|-----------------------------------------------------------------------------------------------------------------------|----------------------------------------------------|
| Product Name:Xospata                                                                                                  |                                                    |
| Diagnosis                                                                                                             | Acute Myeloid Leukemia, Myeloid/Lymphoid Neoplasms |
| Approval Length                                                                                                       | 12 month(s)                                        |
| Therapy Stage                                                                                                         | Reauthorization                                    |
| Guideline Type                                                                                                        | Prior Authorization                                |
| <b>Approval Criteria</b><br><b>1</b> - Patient does not show evidence of progressive disease while on Xospata therapy |                                                    |

|                                                                                                                                                                       |                           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Xospata                                                                                                                                                  |                           |
| Diagnosis                                                                                                                                                             | NCCN Recommended Regimens |
| Approval Length                                                                                                                                                       | 12 month(s)               |
| Therapy Stage                                                                                                                                                         | Initial Authorization     |
| Guideline Type                                                                                                                                                        | Prior Authorization       |
| <b>Approval Criteria</b><br><b>1</b> - Xospata will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium |                           |

|                      |
|----------------------|
| Product Name:Xospata |
|----------------------|



|                                                                                                           |                           |
|-----------------------------------------------------------------------------------------------------------|---------------------------|
| Diagnosis                                                                                                 | NCCN Recommended Regimens |
| Approval Length                                                                                           | 12 month(s)               |
| Therapy Stage                                                                                             | Reauthorization           |
| Guideline Type                                                                                            | Prior Authorization       |
| <b>Approval Criteria</b><br><br><b>1</b> - Documentation of positive clinical response to Xospata therapy |                           |

## 2 . Revision History

| Date      | Notes                                                 |
|-----------|-------------------------------------------------------|
| 3/26/2025 | Updated formularies. Updated initial criteria for AML |

Xphozah



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-199196                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Guideline Name</b> | Xphozah                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Formulary</b>      | Medicaid - Community & State Colorado (ACUCO, ACUCOC)<br>Medicaid - Community & State Hawaii (ACUHI, ACUHIEC)<br>Medicaid - Community & State Maryland (ACUMD)<br>Medicaid - Community & State New Jersey (PSI2300)<br>Medicaid - Community & State New Mexico (ACUNM)<br>Medicaid - Community & State New York (ACUNY, ACUNYM)<br>Medicaid - Community & State New York EPP (ACUNYEPP)<br>Medicaid - Community & State Pennsylvania CHIP (ACUPAC)<br>Medicaid - Community & State Rhode Island (ACURI)<br>Medicaid - Community & State Virginia (ACUVA, ACUVAC, ACUVAEC)<br>Medicaid - Community & State Washington (ACUWA, ACUWAAHE, ACUWAC) |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 4/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                      |                       |
|----------------------|-----------------------|
| Product Name:Xphozah |                       |
| Approval Length      | 12 month(s)           |
| Therapy Stage        | Initial Authorization |

| Guideline Type | Prior Authorization                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                | <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of chronic kidney disease (CKD)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Patient is receiving dialysis</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Serum phosphorus is greater than 6.5 mg/dL (milligrams per deciliter)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>4</b> - Patient has had an inadequate response to at least a 4-week maximally tolerated dose of BOTH of the following phosphate binders as confirmed by claims history or submission of medical records:</p> <p><b>4.1</b> calcium acetate (generic PhosLo)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>4.2</b> sevelamer carbonate (generic Renvela)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>5</b> - Xphozah will be used as add-on therapy</p> <p style="text-align: center;"><b>AND</b></p> <p><b>6</b> - Prescribed by or in consultation with a nephrologist</p> |

|                                                                                                                                                                                                                                                                                                                                            |                     |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Xphozah                                                                                                                                                                                                                                                                                                                       |                     |
| Approval Length                                                                                                                                                                                                                                                                                                                            | 12 month(s)         |
| Therapy Stage                                                                                                                                                                                                                                                                                                                              | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                                                                                                             | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of positive clinical response to Xphozah therapy [e.g., reduction of serum phosphorus towards the normal range (3.5 to 5.5 milligrams per deciliter)]</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Prescribed by or in consultation with a nephrologist</p> |                     |

## 2 . Revision History

| Date      | Notes                                                                         |
|-----------|-------------------------------------------------------------------------------|
| 2/26/2025 | Combined formularies. No changes to clinical criteria. Minor cosmetic update. |

Xpovio



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-211192                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Guideline Name</b> | Xpovio                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Formulary</b>      | Medicaid - Community & State Colorado (ACUCO, ACUCOC)<br>Medicaid - Community & State Hawaii (ACUHI, ACUHIEC)<br>Medicaid - Community & State Indiana (ACUIN)<br>Medicaid - Community & State Maryland (ACUMD)<br>Medicaid - Community & State New Jersey (PSI2300)<br>Medicaid - Community & State New Mexico (ACUNM)<br>Medicaid - Community & State New York (ACUNY, ACUNYM)<br>Medicaid - Community & State New York EPP (ACUNYEPP)<br>Medicaid - Community & State Pennsylvania CHIP (ACUPAC)<br>Medicaid - Community & State Rhode Island (ACURI)<br>Medicaid - Community & State Virginia (ACUVA, ACUVAC, ACUVAEC) |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 4/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                     |                       |
|---------------------|-----------------------|
| Product Name:Xpovio |                       |
| Diagnosis           | Multiple Myeloma      |
| Approval Length     | 12 month(s)           |
| Therapy Stage       | Initial Authorization |

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Prior Authorization |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1 - ALL of the following:</b></p> <p><b>1.1</b> Diagnosis of relapsed or refractory multiple myeloma (RRMM)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>1.2</b> Patient has received at least four prior therapies</p> <p style="text-align: center;"><b>AND</b></p> <p><b>1.3</b> Disease is refractory to ALL of the following:</p> <p style="padding-left: 40px;">Two proteasome inhibitors</p> <p style="padding-left: 40px;">Two immunomodulatory agents</p> <p style="padding-left: 40px;">An anti-CD38 monoclonal antibody</p> <p style="text-align: center;"><b>AND</b></p> <p><b>1.4</b> Used in combination with dexamethasone</p> <p style="text-align: center;"><b>OR</b></p> <p><b>2 - ALL of the following:</b></p> <p><b>2.1</b> Diagnosis of multiple myeloma</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2.2</b> Patient has received at least one prior therapy</p> |                     |

**AND**

**2.3** Used in combination with ONE of the following:

Velcade (bortezomib) and dexamethasone

Darzalex (daratumumab) and dexamethasone

Kyprolis (carfilzomib) and dexamethasone

**OR**

**3** - ALL of the following:

**3.1** Diagnosis of multiple myeloma

**AND**

**3.2** Patient has received at least 2 prior therapies, including an immunomodulatory agent (e.g., lenalidomide, thalidomide) and a proteasome inhibitor (e.g., bortezomib, carfilzomib)

**AND**

**3.3** Patient has demonstrated progression on or within 60 days of completion of the last therapy

**AND**

**3.4** Used in combination with Pomalyst (pomalidomide) and dexamethasone

|                     |                                       |
|---------------------|---------------------------------------|
| Product Name:Xpovio |                                       |
| Diagnosis           | Diffuse Large B-cell Lymphoma (DLBCL) |
| Approval Length     | 12 month(s)                           |
| Therapy Stage       | Initial Authorization                 |

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Prior Authorization |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1 - ONE of the following:</b></p> <p><b>1.1</b> Diagnosis of relapsed or refractory diffuse large B-cell lymphoma (DLBCL) (including histologic transformation of indolent lymphomas to DLBCL)</p> <p style="text-align: center;"><b>OR</b></p> <p><b>1.2</b> Diagnosis of relapsed or refractory HIV (human immunodeficiency virus)-related diffuse large B-cell lymphoma, primary effusion lymphoma, or HHV8-positive diffuse large B-cell lymphoma</p> <p style="text-align: center;"><b>OR</b></p> <p><b>1.3</b> Diagnosis of relapsed or refractory monomorphic B-Cell type post-transplant lymphoproliferative disorder</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2 - Patient has received at least 2 lines of systemic therapies</b></p> |                     |

|                                                                                                                                 |                                                         |
|---------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------|
| Product Name:Xpovio                                                                                                             |                                                         |
| Diagnosis                                                                                                                       | Multiple Myeloma, Diffuse Large B-cell Lymphoma (DLBCL) |
| Approval Length                                                                                                                 | 12 month(s)                                             |
| Therapy Stage                                                                                                                   | Reauthorization                                         |
| Guideline Type                                                                                                                  | Prior Authorization                                     |
| <p><b>Approval Criteria</b></p> <p><b>1 - Patient does not show evidence of progressive disease while on Xpovio therapy</b></p> |                                                         |



|                                                                                                                                         |                           |
|-----------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Xpovio                                                                                                                     |                           |
| Diagnosis                                                                                                                               | NCCN Recommended Regimens |
| Approval Length                                                                                                                         | 12 month(s)               |
| Therapy Stage                                                                                                                           | Initial Authorization     |
| Guideline Type                                                                                                                          | Prior Authorization       |
| <b>Approval Criteria</b><br><br>1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium |                           |

|                                                                                                   |                           |
|---------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Xpovio                                                                               |                           |
| Diagnosis                                                                                         | NCCN Recommended Regimens |
| Approval Length                                                                                   | 12 month(s)               |
| Therapy Stage                                                                                     | Reauthorization           |
| Guideline Type                                                                                    | Prior Authorization       |
| <b>Approval Criteria</b><br><br>1 - Documentation of positive clinical response to Xpovio therapy |                           |

## 2 . Revision History

| Date     | Notes               |
|----------|---------------------|
| 3/6/2025 | Updated formularies |

Xtandi



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-152478                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Guideline Name</b> | Xtandi                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Formulary</b>      | Medicaid - Community & State Colorado (ACUCO, ACUCOC)<br>Medicaid - Community & State Hawaii (ACUHI, ACUHIEC)<br>Medicaid - Community & State Maryland (ACUMD)<br>Medicaid - Community & State New Jersey (PSI2300)<br>Medicaid - Community & State New York EPP (ACUNYEPP)<br>Medicaid - Community & State New York (ACUNY, ACUNYM)<br>Medicaid - Community & State Pennsylvania CHIP (ACUPAC)<br>Medicaid - Community & State Rhode Island (ACURI) |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 9/1/2024 |
|-----------------|----------|

## 1 . Criteria

|                     |                       |
|---------------------|-----------------------|
| Product Name:Xtandi |                       |
| Diagnosis           | Prostate Cancer       |
| Approval Length     | 12 month(s)           |
| Therapy Stage       | Initial Authorization |
| Guideline Type      | Prior Authorization   |

**Approval Criteria**

**1** - Diagnosis of prostate cancer

**AND**

**2** - ONE of the following:

**2.1** Both of the following:

**2.1.1** Disease is castration-resistant

**AND**

**2.1.2** One of the following:

Used in combination with a gonadotropin-releasing hormone (GnRH) analog [e.g., Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix)]

Patient has had bilateral orchiectomy

**OR**

**2.2** Both of the following:

**2.2.1** Disease is metastatic castration-sensitive

**AND**

**2.2.2** One of the following:

Used in combination with a gonadotropin-releasing hormone (GnRH) analog [e.g., Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix)]

Patient has had bilateral orchiectomy

**OR**

**2.3** Disease is non-metastatic castration-sensitive with biochemical recurrence at high risk for metastasis

**AND**

**3** - ONE of the following:

**3.1** BOTH of the following:

**3.1.1** Disease is castration-resistant

**AND**

**3.1.2** ONE of the following:

**3.1.2.1** Failure to BOTH of the following as confirmed by claims history or submission of medical records:

Erleada (apalutamide)

Nubeqa (darolutamide)

**OR**

**3.1.2.2** History of contraindication or intolerance to BOTH of the following (please specify contraindication or intolerance):

Erleada (apalutamide)

Nubeqa (darolutamide)

**OR**

**3.1.2.3** Continuation of ongoing Xtandi therapy

**OR**

**3.2** BOTH of the following:

**3.2.1** Disease is BOTH of the following:

Metastatic

Castration-sensitive

**AND**

**3.2.2** ONE of the following:

**3.2.2.1** Failure to ALL of the following as confirmed by claims history or submission of medical records:

abiraterone (generic Zytiga)

Erleada (apalutamide)

Nubeqa (darolutamide)

**OR**

**3.2.2.2** History of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):

abiraterone (generic Zytiga)

Erleada (apalutamide)

Nubeqa (darolutamide)

**OR**

**3.2.2.3** Continuation of ongoing Xtandi therapy

**OR**

**3.3** BOTH of the following:

**3.3.1** Disease is ALL of the following:

Non-metastatic

Castration-sensitive

Recurrent

High risk for metastasis

**AND**

**3.3.2** ONE of the following:

**3.3.2.1** Failure to abiraterone (generic Zytiga) as confirmed by claims history or submission of medical records

**OR**

**3.3.2.2** History of contraindication or intolerance to abiraterone (generic Zytiga) (please specify contraindication or intolerance)

**OR**

**3.3.2.3** Continuation of ongoing Xtandi therapy

|                     |                     |
|---------------------|---------------------|
| Product Name:Xtandi |                     |
| Diagnosis           | Prostate Cancer     |
| Approval Length     | 12 month(s)         |
| Therapy Stage       | Reauthorization     |
| Guideline Type      | Prior Authorization |

**Approval Criteria**

1 - Patient does not show evidence of progressive disease while on Xtandi therapy

Product Name:Xtandi

|           |                           |
|-----------|---------------------------|
| Diagnosis | NCCN Recommended Regimens |
|-----------|---------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Xtandi

|           |                           |
|-----------|---------------------------|
| Diagnosis | NCCN Recommended Regimens |
|-----------|---------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                 |
|---------------|-----------------|
| Therapy Stage | Reauthorization |
|---------------|-----------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

1 - Documentation of positive clinical response to Xtandi therapy

## 2 . Revision History

|      |       |
|------|-------|
| Date | Notes |
|------|-------|

|           |                                                                                                                                    |
|-----------|------------------------------------------------------------------------------------------------------------------------------------|
| 8/22/2024 | Updated criteria to reflect that for non-metastatic castration-sensitive prostate cancer concomitant use with GnRH is not required |
|-----------|------------------------------------------------------------------------------------------------------------------------------------|



Xuriden



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-356205                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Guideline Name</b> | Xuriden                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Formulary</b>      | Medicaid - Community & State Colorado (ACUCO, ACUCOC)<br>Medicaid - Community & State Hawaii (ACUHI, ACUHIEC)<br>Medicaid - Community & State Maryland (ACUMD)<br>Medicaid - Community & State New Jersey (PSI2300)<br>Medicaid - Community & State New York (ACUNY, ACUNYM)<br>Medicaid - Community & State New York EPP (ACUNYEPP)<br>Medicaid - Community & State Pennsylvania CHIP (ACUPAC)<br>Medicaid - Community & State Rhode Island (ACURI)<br>Medicaid - Community & State Indiana (ACUIN)<br>Medicaid - Community & State Nebraska (ACUNE)<br>Medicaid - Community & State New Mexico (ACUNM)<br>Medicaid - Community & State Pennsylvania (ACUPA)<br>Medicaid - Community & State Virginia (ACUVA, ACUVAC, ACUVAEC) |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 9/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                      |                       |
|----------------------|-----------------------|
| Product Name:Xuriden |                       |
| Approval Length      | 12 month(s)           |
| Therapy Stage        | Initial Authorization |

|                                                                                  |                     |
|----------------------------------------------------------------------------------|---------------------|
| Guideline Type                                                                   | Prior Authorization |
| <b>Approval Criteria</b><br><b>1 - Diagnosis of a hereditary orotic aciduria</b> |                     |

|                                                                                                       |                     |
|-------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Xuriden                                                                                  |                     |
| Approval Length                                                                                       | 12 month(s)         |
| Therapy Stage                                                                                         | Reauthorization     |
| Guideline Type                                                                                        | Prior Authorization |
| <b>Approval Criteria</b><br><b>1 - Documentation of positive clinical response to Xuriden therapy</b> |                     |

## 2 . Revision History

| Date     | Notes                                                  |
|----------|--------------------------------------------------------|
| 8/4/2025 | Combined formularies. No changes to clinical criteria. |

Xyrem, Xywav, Lumryz



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-220254                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Guideline Name</b> | Xyrem, Xywav, Lumryz                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Formulary</b>      | Medicaid - Community & State Colorado (ACUCO, ACUCOC)<br>Medicaid - Community & State Hawaii (ACUHI, ACUHIEC)<br>Medicaid - Community & State New Jersey (PSI2300)<br>Medicaid - Community & State New Mexico (ACUNM)<br>Medicaid - Community & State New York (ACUNY, ACUNYM)<br>Medicaid - Community & State New York EPP (ACUNYEPP)<br>Medicaid - Community & State Pennsylvania CHIP (ACUPAC)<br>Medicaid - Community & State Rhode Island (ACURI)<br>Medicaid - Community & State Virginia (ACUVA, ACUVAC, ACUVAEC) |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 5/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                                                   |                                                     |
|---------------------------------------------------|-----------------------------------------------------|
| Product Name:Xyrem, Sodium Oxybate, Xywav, Lumryz |                                                     |
| Diagnosis                                         | Narcolepsy with Cataplexy (i.e., Narcolepsy Type 1) |
| Approval Length                                   | 12 month(s)                                         |
| Therapy Stage                                     | Initial Authorization                               |
| Guideline Type                                    | Prior Authorization                                 |

### **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes, laboratory values) documenting a diagnosis of narcolepsy with cataplexy (i.e., Narcolepsy Type 1) with BOTH of the following:

**1.1** The patient has daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least three months

**AND**

**1.2** A mean sleep latency of less than or equal to 8 minutes and two or more sleep onset rapid eye movement (REM) periods (SOREMPs) on a Multiple Sleep Latency Test (MSLT) performed according to standard techniques following a normal overnight polysomnogram. A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal polysomnogram may replace one of the SOREMPs on the MSLT

**AND**

**2** - Physician attestation to BOTH of the following:

**2.1** Patient has experienced cataplexy defined as more than one episode of sudden loss of muscle tone with retained consciousness

**AND**

**2.2** Other causes of sleepiness have been ruled out or treated (including but not limited to obstructive sleep apnea, insufficient sleep syndrome, shift work, the effects of substances or medications, or other sleep disorders)

**AND**

**3** - Prescribed by ONE of the following:

Neurologist

Psychiatrist

Sleep Medicine Specialist

Pulmonologist

**AND**

**4 - ONE of the following:**

**4.1** Failure to Wakix (pitolisant) as confirmed by claims history or submission of medical records

**OR**

**4.2** History of contraindication or intolerance to Wakix (pitolisant) (please specify intolerance or contraindication)

|                                                                                                                                                                                                                                                                                                  |                                                     |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------|
| Product Name:Xyrem, Sodium Oxybate, Xywav, Lumryz                                                                                                                                                                                                                                                |                                                     |
| Diagnosis                                                                                                                                                                                                                                                                                        | Narcolepsy with Cataplexy (i.e., Narcolepsy Type 1) |
| Approval Length                                                                                                                                                                                                                                                                                  | 12 month(s)                                         |
| Therapy Stage                                                                                                                                                                                                                                                                                    | Reauthorization                                     |
| Guideline Type                                                                                                                                                                                                                                                                                   | Prior Authorization                                 |
| <p><b>Approval Criteria</b></p> <p><b>1 - Documentation demonstrating a reduction in frequency of cataplexy attacks associated with therapy</b></p> <p><b>OR</b></p> <p><b>2 - Documentation demonstrating reduction in symptoms of excessive daytime sleepiness associated with therapy</b></p> |                                                     |

|                                                   |                                                        |
|---------------------------------------------------|--------------------------------------------------------|
| Product Name:Xyrem, Sodium Oxybate, Xywav, Lumryz |                                                        |
| Diagnosis                                         | Narcolepsy without Cataplexy (i.e., Narcolepsy Type 2) |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                       |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Submission of medical records (e.g., chart notes, lab values) documenting a diagnosis of narcolepsy without cataplexy (i.e., Narcolepsy Type 2) with BOTH of the following:</p> <p><b>1.1</b> The patient has daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least three months</p> <p style="text-align: center;"><b>AND</b></p> <p><b>1.2</b> A mean sleep latency of less than or equal to 8 minutes and two or more sleep onset rapid eye movement (REM) periods (SOREMPs) are found on a Multiple Sleep Latency Test (MSLT) performed according to standard techniques following a normal overnight polysomnogram. A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal polysomnogram may replace one of the SOREMPs on the MSLT</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Physician attestation to BOTH of the following:</p> <p><b>2.1</b> Cataplexy is absent</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2.2</b> Other causes of sleepiness have been ruled out or treated (including but not limited to obstructive sleep apnea, insufficient sleep syndrome, shift work, the effects of substances or medications or their withdrawal, sleep phase disorder, or other sleep disorders)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - ONE of the following:</p> |                       |

**3.1** Failure of BOTH of the following confirmed by claims history or submission of medical records:

**3.1.1** ONE of the following:

Amphetamine based stimulant (e.g., amphetamine, dextroamphetamine)

Methylphenidate based stimulant

**AND**

**3.1.2** ONE of the following:

Modafinil (Provigil)

Armodafinil (Nuvigil)

**OR**

**3.2** History of contraindication or intolerance of ALL of the following (please specify intolerance or contraindication):

Amphetamine based stimulant (e.g., amphetamine, dextroamphetamine)

Methylphenidate based stimulant

Modafinil (Provigil)

Armodafinil (Nuvigil)

**AND**

**4** - ONE of the following:

**4.1** Failure to Sunosi (solriamfetol) as confirmed by claims history or submission of medical records

**OR**

**4.2** History of contraindication or intolerance to Sunosi (solriamfetol) (please specify intolerance or contraindication)

**AND**

**5** - Prescribed by ONE of the following:

Neurologist

Psychiatrist

Sleep Medicine Specialist

Pulmonologist

**Product Name:**Xyrem, Sodium Oxybate, Xywav, Lumryz

|           |                                                        |
|-----------|--------------------------------------------------------|
| Diagnosis | Narcolepsy without Cataplexy (i.e., Narcolepsy Type 2) |
|-----------|--------------------------------------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                 |
|---------------|-----------------|
| Therapy Stage | Reauthorization |
|---------------|-----------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

**1** - Documentation demonstrating reduction in symptoms of excessive daytime sleepiness associated with therapy

**Product Name:**Xywav

|           |                        |
|-----------|------------------------|
| Diagnosis | Idiopathic Hypersomnia |
|-----------|------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|



## **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes, lab values) documenting a diagnosis of idiopathic hypersomnia with both of the following:

**1.1** The patient has daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least three months

**AND**

**1.2** A mean sleep latency of < 8 minutes and fewer than two REM (rapid eye movement) periods (SOREMPs) are found on a MSLT (multiple sleep latency test) performed according to standard techniques following a normal overnight polysomnogram, or no SOREMPs if the REM sleep latency on the preceding polysomnogram was < 15 minutes

**AND**

**2** - Physician attestation that other causes of sleepiness have been ruled out or treated (including but not limited to obstructive sleep apnea, insufficient sleep syndrome, shift work, the effects of substances or medications or their withdrawal, sleep phase disorder, or other sleep disorders)

**AND**

**3** - ONE of the following:

**3.1** Failure of BOTH of the following confirmed by claims history or submission of medical records:

**3.1.1** ONE of the following:

Amphetamine based stimulant (e.g., amphetamine, dextroamphetamine)

Methylphenidate based stimulant

**AND**

**3.1.2** ONE of the following:

Modafinil (Provigil)

Armodafinil (Nuvigil)

**OR**

**3.2** History of contraindication or intolerance of ALL of the following (please specify intolerance or contraindication):

Amphetamine based stimulant (e.g., amphetamine, dextroamphetamine)

Methylphenidate based stimulant

Modafinil (Provigil)

Armodafinil (Nuvigil)

**AND**

**4** - Prescribed by ONE of the following:

Neurologist

Psychiatrist

Sleep medicine specialist

Pulmonologist

|                                                                                                                                                             |                        |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|
| Product Name:Xywav                                                                                                                                          |                        |
| Diagnosis                                                                                                                                                   | Idiopathic Hypersomnia |
| Approval Length                                                                                                                                             | 12 month(s)            |
| Therapy Stage                                                                                                                                               | Reauthorization        |
| Guideline Type                                                                                                                                              | Prior Authorization    |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation demonstrating reduction in symptoms of excessive daytime sleepiness associated with therapy</p> |                        |

## 2 . Revision History

| Date      | Notes                                                 |
|-----------|-------------------------------------------------------|
| 3/19/2025 | Combined formularies. No change to clinical criteria. |

Yonsa



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-217206                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Guideline Name</b> | Yonsa                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Formulary</b>      | Medicaid - Community & State Colorado (ACUCO, ACUCOC)<br>Medicaid - Community & State Hawaii (ACUHI, ACUHIEC)<br>Medicaid - Community & State Indiana (ACUIN)<br>Medicaid - Community & State Maryland (ACUMD)<br>Medicaid - Community & State New Jersey (PSI2300)<br>Medicaid - Community & State New Mexico (ACUNM)<br>Medicaid - Community & State New York EPP (ACUNYEPP)<br>Medicaid - Community & State New York (ACUNY, ACUNYM)<br>Medicaid - Community & State Pennsylvania CHIP (ACUPAC)<br>Medicaid - Community & State Rhode Island (ACURI)<br>Medicaid - Community & State Virginia (ACUVA, ACUVAC, ACUVAEC) |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 5/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                    |                       |
|--------------------|-----------------------|
| Product Name:Yonsa |                       |
| Diagnosis          | Prostate Cancer       |
| Approval Length    | 12 month(s)           |
| Therapy Stage      | Initial Authorization |

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Prior Authorization |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of prostate cancer</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - ONE of the following:</p> <p><b>2.1</b> Disease is metastatic</p> <p style="text-align: center;"><b>OR</b></p> <p><b>2.2</b> Disease is regional node positive (e.g., N1)</p> <p style="text-align: center;"><b>OR</b></p> <p><b>2.3</b> Patient is in a very-high-risk group receiving external beam radiation therapy (EBRT)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Used in combination with methylprednisolone</p> <p style="text-align: center;"><b>AND</b></p> <p><b>4</b> - ONE of the following:</p> <p><b>4.1</b> Used in combination with a gonadotropin-releasing hormone (GnRH) analog [e.g., Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Firmagon (degarelix)]</p> <p style="text-align: center;"><b>OR</b></p> <p><b>4.2</b> Patient has had bilateral orchiectomy</p> |                     |

**AND**

**5** - ONE of the following:

**5.1** Prescriber provides a reason or special circumstance the patient cannot take abiraterone (generic Zytiga)

**OR**

**5.2** Patient is currently on Yonsa therapy

|                                                                                                                                |                     |
|--------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Yonsa                                                                                                             |                     |
| Diagnosis                                                                                                                      | Prostate Cancer     |
| Approval Length                                                                                                                | 12 month(s)         |
| Therapy Stage                                                                                                                  | Reauthorization     |
| Guideline Type                                                                                                                 | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Patient does not show evidence of progressive disease while on Yonsa therapy</p> |                     |

|                                                                                                                                                       |                           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Yonsa                                                                                                                                    |                           |
| Diagnosis                                                                                                                                             | NCCN Recommended Regimens |
| Approval Length                                                                                                                                       | 12 month(s)               |
| Therapy Stage                                                                                                                                         | Initial Authorization     |
| Guideline Type                                                                                                                                        | Prior Authorization       |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium</p> |                           |

|                                                                                                  |                           |
|--------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Yonsa                                                                               |                           |
| Diagnosis                                                                                        | NCCN Recommended Regimens |
| Approval Length                                                                                  | 12 month(s)               |
| Therapy Stage                                                                                    | Reauthorization           |
| Guideline Type                                                                                   | Prior Authorization       |
| <b>Approval Criteria</b><br><br>1 - Documentation of positive clinical response to Yonsa therapy |                           |

## 2 . Revision History

| Date      | Notes                                                  |
|-----------|--------------------------------------------------------|
| 3/17/2025 | Combined formularies. No changes to clinical criteria. |

Yorvipath



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-398223                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Guideline Name</b> | Yorvipath                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Formulary</b>      | Medicaid - Community & State Colorado (ACUCO, ACUCOC)<br>Medicaid - Community & State Hawaii (ACUHI, ACUHIEC)<br>Medicaid - Community & State Maryland (ACUMD)<br>Medicaid - Community & State Nebraska (ACUNE)<br>Medicaid - Community & State New Jersey (PSI2300)<br>Medicaid - Community & State New Mexico (ACUNM)<br>Medicaid - Community & State New York (ACUNY, ACUNYM)<br>Medicaid - Community & State New York EPP (ACUNYEPP)<br>Medicaid - Community & State Pennsylvania CHIP (ACUPAC)<br>Medicaid - Community & State Rhode Island (ACURI)<br>Medicaid - Community & State Virginia (ACUVA, ACUVAC, ACUVAEC)<br>Medicaid - Community & State Washington (ACUWA, ACUWAAHE, ACUWAC)<br>Medicaid - Community & State Pennsylvania (ACUPA) |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 10/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                        |             |
|------------------------|-------------|
| Product Name:Yorvipath |             |
| Approval Length        | 12 month(s) |



|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                       |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1 - Diagnosis of hypoparathyroidism</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>2 - Confirmation of initial diagnosis by both of the following:</b></p> <p><b>2.1</b> Pretreatment low albumin-corrected serum calcium (i.e., less than or equal to 8.5 milligrams per deciliter) confirmed on at least two occasions separated by at least 2 weeks</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2.2</b> Pretreatment undetectable or inappropriately low intact PTH concentration (i.e., less than 20 picograms per milliliter), by second- or third-generation immunoassay, on at least two occasions</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3 - Yorvipath is not being used to treat acute post-surgical hypoparathyroidism</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>4 - Patient is currently on adequate supplemental calcium and active vitamin D (e.g., calcitriol) therapy as evidenced by both of the following:</b></p> <p><b>4.1</b> Albumin-corrected serum calcium 7.8–10.6 micrograms per deciliter</p> <p style="text-align: center;"><b>AND</b></p> <p><b>4.2</b> Serum 25(OH) vitamin D 20–80 nanograms per milliliter</p> |                       |

**AND**

**5** - Prescribed by one of the following:

Endocrinologist

Nephrologist

Product Name:Yorvipath

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                 |
|---------------|-----------------|
| Therapy Stage | Reauthorization |
|---------------|-----------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

### Approval Criteria

**1** - Documentation of positive clinical response [e.g., albumin-corrected serum calcium level in normal range (approximately 8.3-10.6 milligrams per deciliter), independence from conventional therapy (e.g., requiring no active vitamin D, less than or equal to 600 milligrams per day of calcium)]

**AND**

**2** - Prescribed by one of the following:

Endocrinologist

Nephrologist

## 2 . Revision History

| Date      | Notes                                              |
|-----------|----------------------------------------------------|
| 9/17/2025 | Removed IN. (IN will have separate state criteria) |



Zejula



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-406215                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Guideline Name</b> | Zejula                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Formulary</b>      | Medicaid - Community & State Colorado (ACUCO, ACUCOC)<br>Medicaid - Community & State Hawaii (ACUHI, ACUHIEC)<br>Medicaid - Community & State Maryland (ACUMD)<br>Medicaid - Community & State New Jersey (PSI2300)<br>Medicaid - Community & State New York (ACUNY, ACUNYM)<br>Medicaid - Community & State New York EPP (ACUNYEPP)<br>Medicaid - Community & State Pennsylvania CHIP (ACUPAC)<br>Medicaid - Community & State Rhode Island (ACURI)<br>Medicaid - Community & State New Mexico (ACUNM)<br>Medicaid - Community & State Virginia (ACUVA, ACUVAC, ACUVAEC)<br>Medicaid - Community & State Washington (ACUWA, ACUWAAHE, ACUWAC) |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 11/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                     |                |
|---------------------|----------------|
| Product Name:Zejula |                |
| Diagnosis           | Ovarian Cancer |
| Approval Length     | 12 month(s)    |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                       |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1 - Diagnosis of ONE of the following:</b></p> <ul style="list-style-type: none"> <li>Epithelial ovarian cancer</li> <li>Fallopian tube cancer</li> <li>Primary peritoneal cancer</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>2 - Disease is stage II-IV</b></p> <p style="text-align: center;"><b>AND</b></p> <p><b>3 - ONE of the following:</b></p> <p><b>3.1 BOTH of the following:</b></p> <ul style="list-style-type: none"> <li>Maintenance therapy for those who are in complete or partial response after first-line platinum-based chemotherapy</li> <li>Recurrence therapy for platinum-sensitive disease in combination with bevacizumab</li> </ul> <p style="text-align: center;"><b>OR</b></p> <p><b>3.2 BOTH of the following:</b></p> <ul style="list-style-type: none"> <li>Maintenance therapy for those who are in complete or partial response to platinum-based chemotherapy for recurrent disease</li> <li>Disease with a deleterious or suspected deleterious germline BRCA mutation</li> </ul> |                       |

**OR**

**3.3 BOTH of the following:**

Recurrent therapy for platinum-sensitive disease

Used in combination with bevacizumab

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                       |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Zejula                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                       |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Prostate Cancer       |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1 -</b> Diagnosis of castration-resistant distant metastatic (M1) prostate cancer</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2 -</b> Patient is positive for pathogenic BRCA1 or BRCA2 mutation</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3 -</b> Patient has not had treatment since disease progression to metastatic castration-resistant prostate cancer (mCRPC)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>4 - ONE of the following:</b></p> <p>Patient has not received prior docetaxel and prior novel hormone therapy</p> |                       |

Patient had progression on prior docetaxel therapy and has not received prior novel hormone therapy

Patient had progression on prior novel hormone therapy and has not received prior docetaxel therapy

**AND**

**5** - Used in combination with abiraterone or Yonsa (fine-particle abiraterone)

| Product Name:Zejula                                                                                                                                                                                                                                                                                   |                       |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Diagnosis                                                                                                                                                                                                                                                                                             | Uterine Sarcoma       |
| Approval Length                                                                                                                                                                                                                                                                                       | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                         | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                        | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of BRCA-2 (breast cancer) altered uterine leiomyosarcoma (LMS)</p> <p><b>AND</b></p> <p><b>2</b> - Disease is advanced, recurrent/metastatic, or inoperable</p> <p><b>AND</b></p> <p><b>3</b> - Used as second-line or subsequent therapy</p> |                       |

| Product Name:Zejula |                                                  |
|---------------------|--------------------------------------------------|
| Diagnosis           | Ovarian Cancer, Prostate Cancer, Uterine Sarcoma |
| Approval Length     | 12 month(s)                                      |
| Therapy Stage       | Reauthorization                                  |
| Guideline Type      | Prior Authorization                              |

**Approval Criteria**

1 - Patient does not show evidence of progressive disease while on Zejula therapy

Product Name:Zejula

|           |                           |
|-----------|---------------------------|
| Diagnosis | NCCN Recommended Regimens |
|-----------|---------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Zejula

|           |                           |
|-----------|---------------------------|
| Diagnosis | NCCN Recommended Regimens |
|-----------|---------------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                 |
|---------------|-----------------|
| Therapy Stage | Reauthorization |
|---------------|-----------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

1 - Documentation of positive clinical response to Zejula therapy

## 2 . Revision History

|      |       |
|------|-------|
| Date | Notes |
|------|-------|



|           |                                                                                                                 |
|-----------|-----------------------------------------------------------------------------------------------------------------|
| 9/29/2025 | Updated ovarian cancer and prostate cancer criteria. Updated GPI list to remove capsules. Removed IN formulary. |
|-----------|-----------------------------------------------------------------------------------------------------------------|

Zelboraf



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-242242                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Guideline Name</b> | Zelboraf                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Formulary</b>      | Medicaid - Community & State Colorado (ACUCO, ACUCOC)<br>Medicaid - Community & State Hawaii (ACUHI, ACUHIEC)<br>Medicaid - Community & State Indiana (ACUIN)<br>Medicaid - Community & State Maryland (ACUMD)<br>Medicaid - Community & State New Jersey (PSI2300)<br>Medicaid - Community & State New Mexico (ACUNM)<br>Medicaid - Community & State New York (ACUNY, ACUNYM)<br>Medicaid - Community & State New York EPP (ACUNYEPP)<br>Medicaid - Community & State Pennsylvania CHIP (ACUPAC)<br>Medicaid - Community & State Rhode Island (ACURI)<br>Medicaid - Community & State Virginia (ACUVA, ACUVAC, ACUVAEC)<br>Medicaid - Community & State Washington (ACUWA, ACUWAAHE, ACUWAC) |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 6/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                       |             |
|-----------------------|-------------|
| Product Name:Zelboraf |             |
| Diagnosis             | Melanoma    |
| Approval Length       | 12 month(s) |

|                                                                                                                                                                                                                                                      |                       |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                                                                                                                                                                                        | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                       | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - ONE of the following diagnoses:</p> <p>Unresectable melanoma</p> <p>Metastatic melanoma</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Patient is positive for BRAF V600 mutation</p> |                       |

|                                                                                                                                                                                                                                                                                                 |                                      |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|
| Product Name:Zelboraf                                                                                                                                                                                                                                                                           |                                      |
| Diagnosis                                                                                                                                                                                                                                                                                       | Central Nervous System (CNS) Cancers |
| Approval Length                                                                                                                                                                                                                                                                                 | 12 month(s)                          |
| Therapy Stage                                                                                                                                                                                                                                                                                   | Initial Authorization                |
| Guideline Type                                                                                                                                                                                                                                                                                  | Prior Authorization                  |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - ONE of the following:</p> <p><b>1.1</b> BOTH of the following:</p> <p><b>1.1.1</b> Patient has metastatic brain lesions</p> <p style="text-align: center;"><b>AND</b></p> <p><b>1.1.2</b> Zelboraf is active against primary tumor (melanoma)</p> |                                      |

**OR**

**1.2 BOTH** of the following:

**1.2.1** Diagnosis of glioma

**AND**

**1.2.2 ONE** of the following:

Incomplete resection, biopsy, or surgically inaccessible location

Disease is recurrent or progressive

**AND**

**2** - Cancer is positive for BRAF V600E mutation

**AND**

**3** - Used in combination with Cotellic (cobimetinib)

|                                                                                    |                       |
|------------------------------------------------------------------------------------|-----------------------|
| Product Name:Zelboraf                                                              |                       |
| Diagnosis                                                                          | Hairy Cell Leukemia   |
| Approval Length                                                                    | 12 month(s)           |
| Therapy Stage                                                                      | Initial Authorization |
| Guideline Type                                                                     | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of hairy cell leukemia</p> |                       |

|                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                    |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|
| Product Name:Zelboraf                                                                                                                                                                                                                                                                                                                                                                                                           |                                    |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                       | Non-Small Cell Lung Cancer (NSCLC) |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                 | 12 month(s)                        |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                   | Initial Authorization              |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                  | Prior Authorization                |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of non-small cell lung cancer (NSCLC)</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Disease is ONE of the following:</p> <p style="padding-left: 40px;">Metastatic</p> <p style="padding-left: 40px;">Advanced</p> <p style="padding-left: 40px;">Recurrent</p> <p style="text-align: center;"><b>AND</b></p> <p>3 - Cancer is positive for BRAF V600E mutation</p> |                                    |

|                                                                               |                       |
|-------------------------------------------------------------------------------|-----------------------|
| Product Name:Zelboraf                                                         |                       |
| Diagnosis                                                                     | Histiocytic Neoplasms |
| Approval Length                                                               | 12 month(s)           |
| Therapy Stage                                                                 | Initial Authorization |
| Guideline Type                                                                | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of ONE of the following:</p> |                       |

Erdheim-Chester Disease

Langerhans Cell Histiocytosis

**AND**

**2** - Cancer is positive for BRAF V600 mutation

Product Name:Zelboraf

|           |                |
|-----------|----------------|
| Diagnosis | Thyroid Cancer |
|-----------|----------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

### Approval Criteria

**1** - Diagnosis of ONE of the following:

Follicular carcinoma

Oncocytic carcinoma

Papillary carcinoma

**AND**

**2** - ONE of the following:

Unresectable locoregional recurrent disease

Metastatic disease

Persistent disease

**AND**

**3** - ONE of the following:

Patient has symptomatic disease

Patient has progressive disease

**AND**

**4** - Disease is refractory to radioactive iodine

**AND**

**5** - Cancer is positive for BRAF V600 mutation

| Product Name:Zelboraf                                                                                                  |                                                                                          |
|------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------|
| Diagnosis                                                                                                              | Melanoma, CNS Cancers, Hairy Cell Leukemia, NSCLC, Histiocytic Neoplasms, Thyroid Cancer |
| Approval Length                                                                                                        | 12 month(s)                                                                              |
| Therapy Stage                                                                                                          | Reauthorization                                                                          |
| Guideline Type                                                                                                         | Prior Authorization                                                                      |
| <b>Approval Criteria</b><br><b>1</b> - Patient does not show evidence of progressive disease while on Zelboraf therapy |                                                                                          |

| Product Name:Zelboraf |                           |
|-----------------------|---------------------------|
| Diagnosis             | NCCN Recommended Regimens |
| Approval Length       | 12 month(s)               |
| Therapy Stage         | Initial Authorization     |
| Guideline Type        | Prior Authorization       |
|                       |                           |

**Approval Criteria**

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Zelboraf

|                 |                           |
|-----------------|---------------------------|
| Diagnosis       | NCCN Recommended Regimens |
| Approval Length | 12 month(s)               |
| Therapy Stage   | Reauthorization           |
| Guideline Type  | Prior Authorization       |

**Approval Criteria**

1 - Documentation of positive clinical response to Zelboraf therapy

## 2 . Revision History

| Date      | Notes                                                                                                          |
|-----------|----------------------------------------------------------------------------------------------------------------|
| 4/21/2025 | Combined formularies. Minor formatting update in CNS initial auth section, with no changes to clinical intent. |



Zepbound



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                  |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-353196                                                                                                                                                                                                                                                                        |
| <b>Guideline Name</b> | Zepbound                                                                                                                                                                                                                                                                         |
| <b>Formulary</b>      | Medicaid - Community & State Colorado (ACUCO, ACUCOC)<br>Medicaid - Community & State Hawaii (ACUHI, ACUHIEC)<br>Medicaid - Community & State New Jersey (PSI2300)<br>Medicaid - Community & State New Mexico (ACUNM)<br>Medicaid - Community & State Pennsylvania CHIP (ACUPAC) |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 9/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                          |                         |
|--------------------------|-------------------------|
| Product Name:Zepbound    |                         |
| Diagnosis                | Obstructive Sleep Apnea |
| Approval Length          | 6 month(s)              |
| Therapy Stage            | Initial Authorization   |
| Guideline Type           | Prior Authorization     |
| <b>Approval Criteria</b> |                         |

**1** - Treatment is being requested for obstructive sleep apnea (OSA)

**AND**

**2** - Patient is greater than or equal to 18 years of age

**AND**

**3** - Submission of medical records confirming all of the following:

**3.1** Moderate-to-severe obstructive sleep apnea evidenced by both of the following:

**3.1.1** Sleep study

**AND**

**3.1.2** One of the following:

Apnea Hypopnea Index (AHI) greater than or equal to 15

Respiratory Disturbance Index (RDI) greater than or equal to 15

Respiratory Event Index (REI) greater than or equal to 15

**AND**

**3.2** BMI (body mass index) greater than or equal to 30 kg/m<sup>2</sup> (kilograms per square meter) in the past 6 months

**AND**

**3.3** At least one previous unsuccessful dietary effort to lose weight

**AND**

**3.4** One of the following:

**3.4.1** Both of the following:

Patient is currently on positive airway pressure (PAP) therapy for at least 3 consecutive months

Patient is adherent to PAP therapy, defined as greater than or equal to 4 hours of use per night for greater than or equal to 70 percent of nights

**OR**

**3.4.2** Patient is not a candidate for, or is intolerant to, PAP therapy (e.g., upper airway anatomic abnormalities, etc.)

**AND**

**4** - Used in combination with a reduced calorie diet and increased physical activity

**AND**

**5** - Provider attests to both of the following:

Patient counseled on appropriate positional therapy

Patient counseled on avoidance of alcohol and/or sedatives before bedtime

**AND**

**6** - Patient does NOT have a diagnosis of diabetes or HgA1c (hemoglobin A1c) greater than 6.5%

**AND**

**7** - Prescriber attests the patient does NOT have any one of the following:

Planned surgery for sleep apnea or obesity

Significant craniofacial abnormalities

A diagnosis of central or mixed sleep apnea

**AND**

**8** - Prescribed by, or in consultation with, a sleep specialist

| Product Name:Zepbound                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                      |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Obstructive Sleep Apnea                                                                                                                                                                                                                                              |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | For patients who have been on Zepbound therapy for fewer than 52 weeks of consecutive therapy, authorization of 6 months; OR for patients who have been on Zepbound therapy for greater than or equal to 52 weeks of consecutive therapy, authorization of 12 months |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Reauthorization                                                                                                                                                                                                                                                      |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Prior Authorization                                                                                                                                                                                                                                                  |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - One of the following:</p> <p><b>1.1</b> If patient has been on Zepbound for less than 52 weeks of consecutive therapy, submission of medical records confirming a decrease from baseline in one of the following:</p> <p>Apnea Hypopnea Index (AHI)</p> <p>Respiratory Disturbance Index (RDI)</p> <p>Respiratory Event Index (REI)</p> <p><b>OR</b></p> <p><b>1.2</b> If patient has been on Zepbound for greater than or equal to 52 weeks of consecutive therapy, submission of medical records confirming a 50% decrease from baseline in one of the following:</p> |                                                                                                                                                                                                                                                                      |

Apnea Hypopnea Index (AHI)

Respiratory Disturbance Index (RDI)

Respiratory Event Index (REI)

**AND**

**2** - Patient has had a weight loss of greater than or equal to 10% of baseline body weight

**AND**

**3** - Used in combination with a reduced calorie diet and increased physical activity

**AND**

**4** - Patient does NOT have a diagnosis of diabetes or HgA1c (hemoglobin A1c) greater than 6.5%

**AND**

**5** - Patient continues to require treatment for obstructive sleep apnea

|                                                                                                                                                                     |                     |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Zepbound                                                                                                                                               |                     |
| Diagnosis                                                                                                                                                           | Weight Loss         |
| Guideline Type                                                                                                                                                      | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Zepbound when used solely for the treatment of weight loss is excluded and is to be denied as a benefit exclusion</p> |                     |

## 2 . Revision History

| Date     | Notes                                                                                          |
|----------|------------------------------------------------------------------------------------------------|
| 8/1/2025 | Updated GPIs. Updated reauth criteria to clarify HgA1c is to be greater than or equal to 6.5%. |

Zeposia



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-208215                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Guideline Name</b> | Zeposia                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Formulary</b>      | Medicaid - Community & State Colorado (ACUCO, ACUCOC)<br>Medicaid - Community & State Hawaii (ACUHI, ACUHIEC)<br>Medicaid - Community & State Maryland (ACUMD)<br>Medicaid - Community & State New Jersey (PSI2300)<br>Medicaid - Community & State New Mexico (ACUNM)<br>Medicaid - Community & State New York (ACUNY, ACUNYM)<br>Medicaid - Community & State New York EPP (ACUNYEPP)<br>Medicaid - Community & State Pennsylvania CHIP (ACUPAC)<br>Medicaid - Community & State Rhode Island (ACURI) |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 4/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                      |                       |
|----------------------|-----------------------|
| Product Name:Zeposia |                       |
| Diagnosis            | Multiple Sclerosis    |
| Approval Length      | 12 month(s)           |
| Therapy Stage        | Initial Authorization |
| Guideline Type       | Prior Authorization   |

### Approval Criteria

1 - Diagnosis of multiple sclerosis (MS)

**AND**

2 - ONE of the following:

2.1 BOTH of the following:

2.1.1 Failure to a trial of a preferred\* dimethyl fumarate product, as confirmed by claims history or submission of medical records

**AND**

2.1.2 Failure to a trial of at least ONE additional preferred\* alternative, as confirmed by claims history or submission of medical records

**OR**

2.2 History of intolerance or contraindication to ALL preferred\* alternatives (please specify intolerance or contraindication)

**OR**

2.3 Patient is currently on Zeposia therapy as confirmed by claims history or submission of medical records

Notes

\*PDL links are in Table 1 of Background.

|                      |                     |
|----------------------|---------------------|
| Product Name:Zeposia |                     |
| Diagnosis            | Multiple Sclerosis  |
| Approval Length      | 12 month(s)         |
| Therapy Stage        | Reauthorization     |
| Guideline Type       | Prior Authorization |



**Approval Criteria**

1 - Documentation of positive clinical response to Zeposia therapy

Product Name:Zeposia

|           |                    |
|-----------|--------------------|
| Diagnosis | Ulcerative Colitis |
|-----------|--------------------|

|                 |             |
|-----------------|-------------|
| Approval Length | 12 month(s) |
|-----------------|-------------|

|               |                       |
|---------------|-----------------------|
| Therapy Stage | Initial Authorization |
|---------------|-----------------------|

|                |                     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |
|----------------|---------------------|

**Approval Criteria**

1 - ALL of the following:

1.1 Diagnosis of moderately to severely active ulcerative colitis (UC)

**AND**

1.2 ONE of the following:

1.2.1 Patient has had prior or concurrent inadequate response to a therapeutic course of oral corticosteroids and/or immunosuppressants (e.g., azathioprine, 6-mercaptopurine) as confirmed by claims history or submission of medical records

**OR**

1.2.2 Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of ulcerative colitis as confirmed by claims history or submission of medical records [e.g., adalimumab, Simponi (golimumab), ustekinumab, Xeljanz (tofacitinib), Rinvoq (upadacitinib)]

**AND**

1.3 Patient is not receiving Zeposia in combination with a targeted immunomodulator [e.g.,

adalimumab, Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), ustekinumab, Skyrizi (risankizumab), Omvoh (mirikizumab-mrkz), Entyvio (vedolizumab)]

**AND**

**1.4** ONE of the following:

**1.4.1** Failure to ONE of the preferred adalimumab products\* as confirmed by claims history or submission of medical records

**OR**

**1.4.2** History of intolerance or contraindication to ONE of the preferred adalimumab products\* (please specify intolerance or contraindication)

**AND**

**1.5** Prescribed by or in consultation with a gastroenterologist

**OR**

**2** - ALL of the following:

**2.1** Patient is currently on Zeposia therapy as confirmed by claims history or submission of medical records

**AND**

**2.2** Diagnosis of moderately to severely active ulcerative colitis

**AND**

**2.3** Patient is not receiving Zeposia in combination with a targeted immunomodulator [e.g., adalimumab, Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), ustekinumab, Skyrizi (risankizumab), Omvoh (mirikizumab-mrkz), Entyvio (vedolizumab)]

**AND**

**2.4** Prescribed by or in consultation with a gastroenterologist

|       |                                          |
|-------|------------------------------------------|
| Notes | *PDL links are in Table 1 of Background. |
|-------|------------------------------------------|

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                     |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Zeposia                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                     |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Ulcerative Colitis  |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 12 month(s)         |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p>1 - Documentation of positive clinical response to Zeposia therapy</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Patient is not receiving Zeposia in combination with a targeted immunomodulator [e.g., adalimumab, Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), ustekinumab, Skyrizi (risankizumab), Omvoh (mirikizumab-mrkz), Entyvio (vedolizumab)]</p> |                     |

## 2 . Background

|                                                                                                                                                                                                                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Benefit/Coverage/Program Information</b>                                                                                                                                                                                                                                                 |
| <p><b>Table 1. PDL links</b></p> <p>CO: <a href="https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html">https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html</a></p> |

HI: <https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html>

MD: <https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-cp-pharmacy.html>

NJ: <https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html>

NM: <https://www.uhcprovider.com/en/health-plans-by-state/new-mexico-health-plans/nm-comm-plan-home/nm-cp-pharmacy.html>

NY: <https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html>

PA: <https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP>

RI: <https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html>

### 3 . Revision History

| Date     | Notes                                                                                               |
|----------|-----------------------------------------------------------------------------------------------------|
| 3/5/2025 | Updated formularies. Replaced Stelara with ustekinumab throughout.<br>Updated safety check language |

Zilbrysq



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-418213                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Guideline Name</b> | Zilbrysq                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Formulary</b>      | <ul style="list-style-type: none"> <li>• Medicaid - Community &amp; State Colorado (ACUCO, ACUCOC)</li> <li>• Medicaid - Community &amp; State Hawaii (ACUHI, ACUHIEC)</li> <li>• Medicaid - Community &amp; State Maryland (ACUMD)</li> <li>• Medicaid - Community &amp; State New Jersey (PSI2300)</li> <li>• Medicaid - Community &amp; State New York (ACUNY, ACUNYM)</li> <li>• Medicaid - Community &amp; State New York EPP (ACUNYEPP)</li> <li>• Medicaid - Community &amp; State Pennsylvania CHIP (ACUPAC)</li> <li>• Medicaid - Community &amp; State Rhode Island (ACURI)</li> <li>• Medicaid - Community &amp; State Indiana (ACUIN)</li> <li>• Medicaid - Community &amp; State Nebraska (ACUNE)</li> <li>• Medicaid - Community &amp; State New Mexico (ACUNM)</li> <li>• Medicaid - Community &amp; State Pennsylvania (ACUPA)</li> <li>• Medicaid - Community &amp; State Virginia (ACUVA, ACUVAC, ACUVAEC)</li> <li>•</li> </ul> |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 11/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                       |             |
|-----------------------|-------------|
| Product Name:Zilbrysq |             |
| Approval Length       | 12 month(s) |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                       |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Submission of medical records (e.g., chart notes, laboratory values, etc.) confirming ALL of the following:</p> <p><b>1.1</b> Diagnosis of generalized myasthenia gravis (gMG)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>1.2</b> Positive serologic test for anti-AChR antibodies</p> <p style="text-align: center;"><b>AND</b></p> <p><b>1.3</b> Patient has a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of class II, III, or IV at initiation of therapy</p> <p style="text-align: center;"><b>AND</b></p> <p><b>1.4</b> Patient has a Myasthenia Gravis Activities of Daily Living scale (MG-ADL) total score greater than or equal to 6 at initiation of therapy</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - ONE of the following:</p> <p><b>2.1</b> History of failure of at least two immunosuppressive agents over the course of at least 12 months (e.g., azathioprine, corticosteroids, cyclosporine, methotrexate, mycophenolate, etc.) as confirmed by claims history or submission of medical records</p> <p style="text-align: center;"><b>OR</b></p> <p><b>2.2</b> Patient has a history of failure of at least one immunosuppressive therapy (as confirmed by claims history or submission of medical records) and has required four or more courses of</p> |                       |

plasmapheresis/ plasma exchanges and/or intravenous immune globulin over the course of at least 12 months without symptom control

**OR**

**2.3** Contraindication or intolerance to at least two immunosuppressive agents (please specify contraindication or intolerance)

**AND**

**3** - Patient is not receiving Zilbrysq in combination with another complement inhibitor [e.g., Soliris (eculizumab), Ultomiris (ravulizumab-cwvz)] or a neonatal Fc receptor blocker [e.g., Rystiggo (rozanolixizumab-noli), Vyvgart (efgartigimod alfa-fcab), Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc)]

**AND**

**4** - Prescribed by, or in consultation with, a neurologist

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                     |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Zilbrysq                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                     |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 12 month(s)         |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Submission of medical records (e.g., chart notes, laboratory tests) to demonstrate a positive clinical response from baseline as demonstrated by at least ALL of the following:</p> <p><b>1.1</b> Improvement and/or maintenance of at least a 2-point improvement (reduction in score) in the MG-ADL score from pre-treatment baseline</p> <p><b>AND</b></p> <p><b>1.2</b> Reduction in signs and symptoms of myasthenia gravis</p> |                     |

**AND**

**1.3** Maintenance, reduction, or discontinuation of dose(s) of baseline immunosuppressive therapy (IST) prior to starting Zilbrysq\*

**AND**

**2** - Patient is not receiving Zilbrysq in combination with another complement inhibitor [e.g., Soliris (eculizumab), Ultomiris (ravulizumab-cwvz)] or a neonatal Fc receptor blocker [e.g., Rystiggo (rozanolixizumab-noli), Vyvgart (efgartigimod alfa-fcab), Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc)]

**AND**

**3** - Prescribed by, or in consultation with, a neurologist

|       |                                                                                                                                                                                                      |
|-------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Notes | *Add on, dose escalation of IST, or additional rescue therapy from baseline to treat myasthenia gravis or exacerbation of symptoms while on Zilbrysq therapy will be considered as treatment failure |
|-------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

## 2 . Revision History

| Date      | Notes                                                                                                     |
|-----------|-----------------------------------------------------------------------------------------------------------|
| 10/8/2025 | Reordered formularies and removed ACUAZ/ACUAZEC as they will follow FFS/state criteria for eff 11/1/2025. |



Zokinvy



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-267195                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Guideline Name</b> | Zokinvy                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Formulary</b>      | Medicaid - Community & State Colorado (ACUCO, ACUCOC)<br>Medicaid - Community & State Hawaii (ACUHI, ACUHIEC)<br>Medicaid - Community & State Maryland (ACUMD)<br>Medicaid - Community & State New Jersey (PSI2300)<br>Medicaid - Community & State New York EPP (ACUNYEPP)<br>Medicaid - Community & State New York (ACUNY, ACUNYM)<br>Medicaid - Community & State Pennsylvania CHIP (ACUPAC)<br>Medicaid - Community & State Rhode Island (ACURI)<br>Medicaid - Community & State Arizona (ACUAZ, ACUAZEC)<br>Medicaid - Community & State Virginia (ACUVA, ACUVAC, ACUVAEC)<br>Medicaid - Community & State Pennsylvania (ACUPA)<br>Medicaid - Community & State Nebraska (ACUNE)<br>Medicaid - Community & State New Mexico (ACUNM) |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 7/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                      |                                      |
|----------------------|--------------------------------------|
| Product Name:Zokinvy |                                      |
| Diagnosis            | Hutchinson-Gilford Progeria Syndrome |
| Approval Length      | 12 month(s)                          |

|                                                                                          |                     |
|------------------------------------------------------------------------------------------|---------------------|
| Guideline Type                                                                           | Prior Authorization |
| <b>Approval Criteria</b><br><b>1 - Diagnosis of Hutchinson-Gilford Progeria Syndrome</b> |                     |

|                                                                                                                                                                                                                                                                                                                                                             |                         |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|
| Product Name:Zokinvy                                                                                                                                                                                                                                                                                                                                        |                         |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                   | Progeroid Laminopathies |
| Approval Length                                                                                                                                                                                                                                                                                                                                             | 12 month(s)             |
| Guideline Type                                                                                                                                                                                                                                                                                                                                              | Prior Authorization     |
| <b>Approval Criteria</b><br><b>1 - Diagnosis of processing deficient Progeroid laminopathy</b><br><br><p style="text-align: center;"><b>AND</b></p> <b>2 - Documentation of ONE of the following:</b><br><br>Heterozygous LMNA (gene) mutation with progerin-like protein accumulation<br><br>Homozygous or compound heterozygous ZMPSTE24 (gene) mutations |                         |

## 2 . Revision History

| Date      | Notes                              |
|-----------|------------------------------------|
| 5/14/2025 | Updated formularies to add PA CAID |

Zolanza



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-117476                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Guideline Name</b> | Zolanza                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Formulary</b>      | Medicaid - Community & State Colorado (ACUCO, ACUCOC)<br>Medicaid - Community & State Hawaii (ACUHI, ACUHIEC)<br>Medicaid - Community & State Maryland (ACUMD)<br>Medicaid - Community & State New Jersey (PSI2300)<br>Medicaid - Community & State New York EPP (ACUNYEPP)<br>Medicaid - Community & State New York (ACUNY, ACUNYM)<br>Medicaid - Community & State Pennsylvania CHIP (ACUPAC)<br>Medicaid - Community & State Rhode Island (ACURI) |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 1/1/2023 |
|-----------------|----------|

## 1 . Criteria

|                      |                           |
|----------------------|---------------------------|
| Product Name:Zolanza |                           |
| Diagnosis            | Cutaneous T-Cell Lymphoma |
| Approval Length      | 12 month(s)               |
| Therapy Stage        | Initial Authorization     |
| Guideline Type       | Prior Authorization       |

**Approval Criteria**

**1** - Diagnosis of cutaneous T-cell lymphoma (CTCL)

**AND**

**2** - Patient has progressive, persistent, or recurrent disease on or following two systemic therapies [e.g., Adcetris (brentuximab vedotin), bexarotene, interferon alfa-db, interferon gamma-1b, methotrexate, Poteligeo (mogamulizumab), romidepsin]

Product Name:Zolinza

|                 |                           |
|-----------------|---------------------------|
| Diagnosis       | Cutaneous T-Cell Lymphoma |
| Approval Length | 12 month(s)               |
| Therapy Stage   | Reauthorization           |
| Guideline Type  | Prior Authorization       |

**Approval Criteria**

**1** - Patient does not show evidence of progressive disease while on Zolinza therapy

Product Name:Zolinza

|                 |                           |
|-----------------|---------------------------|
| Diagnosis       | NCCN Recommended Regimens |
| Approval Length | 12 month(s)               |
| Therapy Stage   | Initial Authorization     |
| Guideline Type  | Prior Authorization       |

**Approval Criteria**

**1** - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

|                                                                                                    |                           |
|----------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Zolinza                                                                               |                           |
| Diagnosis                                                                                          | NCCN Recommended Regimens |
| Approval Length                                                                                    | 12 month(s)               |
| Therapy Stage                                                                                      | Reauthorization           |
| Guideline Type                                                                                     | Prior Authorization       |
| <b>Approval Criteria</b><br><br>1 - Documentation of positive clinical response to Zolinza therapy |                           |

## 2 . Revision History

| Date       | Notes                                                 |
|------------|-------------------------------------------------------|
| 11/30/2022 | Combined formularies. No changes to clinical criteria |

Zoryve



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-401280                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Guideline Name</b> | Zoryve                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Formulary</b>      | Medicaid - Community & State Colorado (ACUCO, ACUCOC)<br>Medicaid - Community & State Hawaii (ACUHI, ACUHIEC)<br>Medicaid - Community & State Maryland (ACUMD)<br>Medicaid - Community & State New Jersey (PSI2300)<br>Medicaid - Community & State New York (ACUNY, ACUNYM)<br>Medicaid - Community & State New York EPP (ACUNYEPP)<br>Medicaid - Community & State Pennsylvania CHIP (ACUPAC)<br>Medicaid - Community & State Rhode Island (ACURI)<br>Medicaid - Community & State New Mexico (ACUNM) |

### Guideline Note:

|                 |           |
|-----------------|-----------|
| Effective Date: | 10/1/2025 |
|-----------------|-----------|

## 1 . Criteria

|                                              |                       |
|----------------------------------------------|-----------------------|
| Product Name: Zoryve 0.3% cream, Zoryve foam |                       |
| Diagnosis                                    | Plaque Psoriasis      |
| Approval Length                              | 12 month(s)           |
| Therapy Stage                                | Initial Authorization |
| Guideline Type                               | Prior Authorization   |

## **Approval Criteria**

**1** - Diagnosis of plaque psoriasis

**AND**

**2** - ONE of the following:

**2.1** Submission of medical records or claims history confirming failure to a minimum duration of a 4-week trial to TWO of the following topical therapies:

Corticosteroids (e.g., betamethasone, clobetasol, desonide)

Vitamin D analogs (e.g., calcitriol, calcipotriene)

Tazarotene

Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)

Anthralin

Coal tar

**OR**

**2.2** History of intolerance or contraindication to ALL of the following topical therapies (please specify intolerance or contraindication):

Corticosteroids (e.g., betamethasone, clobetasol, desonide)

Vitamin D analogs (e.g., calcitriol, calcipotriene)

Tazarotene

Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)

Anthralin

Coal tar

**AND**

**3** - Patient is not receiving the requested medication in combination with a targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                     |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Zoryve 0.3% cream, Zoryve foam                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                     |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Plaque Psoriasis    |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 12 month(s)         |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of positive clinical response to therapy</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - Patient is not receiving the requested medication in combination with a targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]</p> |                     |

|                          |                       |
|--------------------------|-----------------------|
| Product Name:Zoryve foam |                       |
| Diagnosis                | Seborrheic dermatitis |
| Approval Length          | 12 month(s)           |
| Therapy Stage            | Initial Authorization |
| Guideline Type           | Prior Authorization   |



## **Approval Criteria**

**1** - Diagnosis of seborrheic dermatitis

**AND**

**2** - ONE of the following:

**2.1** Submission of medical records or claims history confirming failure to a minimum duration of a 4-week trial to TWO of the following topical therapies:

Topical corticosteroids (e.g., betamethasone, hydrocortisone)

Topical, shampoo, or systemic antifungals (e.g., ketoconazole, ciclopirox, itraconazole)

Topical calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)

**OR**

**2.2** History of intolerance or contraindication to ALL of the following topical therapies (please specify intolerance or contraindication):

Topical corticosteroids (e.g., betamethasone, hydrocortisone)

Topical, shampoo, or systemic antifungals (e.g., ketoconazole, ciclopirox, itraconazole)

Topical calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)

**AND**

**3** - Patient is not receiving Zoryve foam in combination with either of the following:

Biologic immunomodulator [e.g., Dupixent (dupilumab), Adbry (tralokinumab-ldrm)]

Janus kinase inhibitor [e.g., Rinvoq (upadacitinib), Xeljanz/XR (tofacitinib), Opzelura (topical ruxolitinib), Cibinqo (abrocitinib)]

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                       |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Zoryve foam                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                       |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Seborrheic Dermatitis |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Reauthorization       |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Documentation of positive clinical response to therapy</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Patient is not receiving Zoryve foam in combination with either of the following:</p> <p style="padding-left: 40px;">Biologic immunomodulator [e.g., Dupixent (dupilumab), Adbry (tralokinumab-ldrm)]</p> <p style="padding-left: 40px;">Janus kinase inhibitor [e.g., Rinvoq (upadacitinib), Xeljanz/XR (tofacitinib), Opzelura (topical ruxolitinib), Cibinqo (abrocitinib)]</p> |                       |

|                                                                                                                                                                           |                       |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Zoryve 0.15% cream                                                                                                                                           |                       |
| Diagnosis                                                                                                                                                                 | Atopic Dermatitis     |
| Approval Length                                                                                                                                                           | 12 month(s)           |
| Therapy Stage                                                                                                                                                             | Initial Authorization |
| Guideline Type                                                                                                                                                            | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of mild to moderate atopic dermatitis</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - ONE of the following:</p> |                       |

**2.1** For mild atopic dermatitis:

**2.1.1** Submission of medical records or claims history confirming failure to TWO of the following topical therapeutic classes:

A topical corticosteroid [e.g., DesOwen (desonide), hydrocortisone] (any potency)

One topical calcineurin inhibitor [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)]

Eucrisa (crisaborole)

**OR**

**2.1.2** History of intolerance or contraindication to ALL of the following topical therapies (please specify intolerance or contraindication):

A topical corticosteroid [e.g., DesOwen (desonide), hydrocortisone] (any potency)

One topical calcineurin inhibitor [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)]

Eucrisa (crisaborole)

**OR**

**2.2** For moderate atopic dermatitis:

**2.2.1** Submission of medical records or claims history confirming failure to TWO of the following topical therapeutic classes:

A topical corticosteroid of at least a medium- to high-potency [e.g., Elocon (mometasone furoate), Synalar (fluocinolone acetonide), Lidex (fluocinonide)]

One topical calcineurin inhibitor [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)]

Eucrisa (crisaborole)

**OR**

**2.2.2** History of intolerance or contraindication to ALL of the following topical therapies (please specify intolerance or contraindication):

A topical corticosteroid of at least a medium- to high-potency [e.g., Elocon (mometasone furoate), Synalar (fluocinolone acetonide), Lidex (fluocinonide)]

One topical calcineurin inhibitor [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)]

Eucrisa (crisaborole)

**AND**

**3** - Patient is not receiving Zoryve 0.15% cream in combination with a targeted immunomodulator [e.g., Adbry (tralokinumab-ldrm), Cibinqo (abrocitinib), Dupixent (dupilumab), Rinvoq (upadacitinib)]

|                                                                                                                                                                                                                                                                                                                                               |                     |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Zoryve 0.15% cream                                                                                                                                                                                                                                                                                                               |                     |
| Diagnosis                                                                                                                                                                                                                                                                                                                                     | Atopic Dermatitis   |
| Approval Length                                                                                                                                                                                                                                                                                                                               | 12 month(s)         |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                 | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Documentation of positive clinical response to therapy</p> <p><b>AND</b></p> <p><b>2</b> - Patient is not receiving Zoryve 0.15% cream in combination with a targeted immunomodulator [e.g., Adbry (tralokinumab-ldrm), Cibinqo (abrocitinib), Dupixent (dupilumab), Rinvoq (upadacitinib)]</p> |                     |

## 2 . Revision History

| Date      | Notes                                          |
|-----------|------------------------------------------------|
| 9/22/2025 | Added Zoryve foam to plaque psoriasis criteria |



Zurzuva



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-164996                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Guideline Name</b> | Zurzuva                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Formulary</b>      | Medicaid - Community & State Colorado (ACUCO, ACUCOC)<br>Medicaid - Community & State Hawaii (ACUHI, ACUHIEC)<br>Medicaid - Community & State New Jersey (PSI2300)<br>Medicaid - Community & State New York (ACUNY, ACUNYM)<br>Medicaid - Community & State New York EPP (ACUNYEPP)<br>Medicaid - Community & State Pennsylvania CHIP (ACUPAC)<br>Medicaid - Community & State Rhode Island (ACURI)<br>Medicaid - Community & State Nebraska (ACUNE)<br>Medicaid - Community & State Washington (ACUWA, ACUWAAHE, ACUWAC) |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 3/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                      |                     |
|----------------------|---------------------|
| Product Name:Zurzuva |                     |
| Approval Length      | 1 month(s)          |
| Guideline Type       | Prior Authorization |
|                      |                     |

**Approval Criteria**

1 - Diagnosis of postpartum depression (PPD)

**AND**

2 - Onset of current depressive episode was during the third trimester or within 4 weeks postpartum

**2 . Revision History**

| Date      | Notes                                                 |
|-----------|-------------------------------------------------------|
| 2/11/2025 | Updated formularies. No changes to clinical criteria. |

Zydelig



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-159292                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Guideline Name</b> | Zydelig                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Formulary</b>      | Medicaid - Community & State Hawaii (ACUHI, ACUHIEC)<br>Medicaid - Community & State Maryland (ACUMD)<br>Medicaid - Community & State New Jersey (PSI2300)<br>Medicaid - Community & State New York EPP (ACUNYEPP)<br>Medicaid - Community & State New York (ACUNY, ACUNYM)<br>Medicaid - Community & State Pennsylvania CHIP (ACUPAC)<br>Medicaid - Community & State Rhode Island (ACURI)<br>Medicaid - Community & State Colorado (ACUCO, ACUCOC) |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 8/1/2023 |
|-----------------|----------|

## 1 . Criteria

|                      |                                                                     |
|----------------------|---------------------------------------------------------------------|
| Product Name:Zydelig |                                                                     |
| Diagnosis            | Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) |
| Approval Length      | 12 month(s)                                                         |
| Therapy Stage        | Initial Authorization                                               |
| Guideline Type       | Prior Authorization                                                 |



**Approval Criteria**

1 - Diagnosis of chronic lymphocytic leukemia (CLL)/ small lymphocytic lymphoma (SLL)

**AND**

2 - ONE of the following:

Disease has relapsed

Disease is refractory

Product Name:Zydelig

|                 |                                                                     |
|-----------------|---------------------------------------------------------------------|
| Diagnosis       | Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) |
| Approval Length | 12 month(s)                                                         |
| Therapy Stage   | Reauthorization                                                     |
| Guideline Type  | Prior Authorization                                                 |

**Approval Criteria**

1 - Patient does not show evidence of progressive disease while on Zydelig therapy

Product Name:Zydelig

|                 |                           |
|-----------------|---------------------------|
| Diagnosis       | NCCN Recommended Regimens |
| Approval Length | 12 month(s)               |
| Therapy Stage   | Initial Authorization     |
| Guideline Type  | Prior Authorization       |

**Approval Criteria**

**1** - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

|                                                                                                    |                           |
|----------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Zydelig                                                                               |                           |
| Diagnosis                                                                                          | NCCN Recommended Regimens |
| Approval Length                                                                                    | 12 month(s)               |
| Therapy Stage                                                                                      | Reauthorization           |
| Guideline Type                                                                                     | Prior Authorization       |
| <b>Approval Criteria</b><br><br>1 - Documentation of positive clinical response to Zydelig therapy |                           |

## 2 . Revision History

| Date      | Notes                |
|-----------|----------------------|
| 11/5/2024 | Updated CO cag to SP |

Zykadia



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-228200                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Guideline Name</b> | Zykadia                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Formulary</b>      | Medicaid - Community & State Colorado (ACUCO, ACUCOC)<br>Medicaid - Community & State Hawaii (ACUHI, ACUHIEC)<br>Medicaid - Community & State Indiana (ACUIN)<br>Medicaid - Community & State Maryland (ACUMD)<br>Medicaid - Community & State New Jersey (PSI2300)<br>Medicaid - Community & State New Mexico (ACUNM)<br>Medicaid - Community & State New York (ACUNY, ACUNYM)<br>Medicaid - Community & State New York EPP (ACUNYEPP)<br>Medicaid - Community & State Pennsylvania CHIP (ACUPAC)<br>Medicaid - Community & State Rhode Island (ACURI)<br>Medicaid - Community & State Virginia (ACUVA, ACUVAC, ACUVAEC) |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 5/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                      |                                    |
|----------------------|------------------------------------|
| Product Name:Zykadia |                                    |
| Diagnosis            | Non-Small Cell Lung Cancer (NSCLC) |
| Approval Length      | 12 month(s)                        |
| Therapy Stage        | Initial Authorization              |

| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Prior Authorization |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of non-small cell lung cancer (NSCLC)</p> <p style="text-align: center;"><b>AND</b></p> <p><b>2</b> - ONE of the following:</p> <p style="padding-left: 40px;">Disease is metastatic</p> <p style="padding-left: 40px;">Disease is recurrent</p> <p style="padding-left: 40px;">Disease is advanced</p> <p style="text-align: center;"><b>AND</b></p> <p><b>3</b> - Tumor is ALK (anaplastic lymphoma kinase)-positive</p> |                     |

|                                                                                                                                                             |                       |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Zykadia                                                                                                                                        |                       |
| Diagnosis                                                                                                                                                   | Soft Tissue Sarcoma   |
| Approval Length                                                                                                                                             | 12 month(s)           |
| Therapy Stage                                                                                                                                               | Initial Authorization |
| Guideline Type                                                                                                                                              | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p><b>1</b> - Diagnosis of inflammatory myofibroblastic tumor (IMT) with anaplastic lymphoma kinase (ALK) translocation</p> |                       |

|                      |                                      |
|----------------------|--------------------------------------|
| Product Name:Zykadia |                                      |
| Diagnosis            | Central Nervous System (CNS) Cancers |

|                                                                                                                                                                                                                                     |                       |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Approval Length                                                                                                                                                                                                                     | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                       | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                      | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of metastatic brain cancer from non-small cell lung cancer (NSCLC)</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Tumor is anaplastic lymphoma kinase (ALK)-positive</p> |                       |

|                                                                                                                                                                                                                 |                       |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Zykadia                                                                                                                                                                                            |                       |
| Diagnosis                                                                                                                                                                                                       | Histiocytic Neoplasms |
| Approval Length                                                                                                                                                                                                 | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                   | Initial Authorization |
| Guideline Type                                                                                                                                                                                                  | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Diagnosis of Erdheim-Chester Disease</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Disease is positive for anaplastic lymphoma kinase (ALK) rearrangement</p> |                       |

|                      |                                |
|----------------------|--------------------------------|
| Product Name:Zykadia |                                |
| Diagnosis            | Anaplastic Large Cell Lymphoma |
| Approval Length      | 12 month(s)                    |
| Therapy Stage        | Initial Authorization          |
| Guideline Type       | Prior Authorization            |

**Approval Criteria**

1 - Diagnosis of anaplastic large cell lymphoma

**AND**

2 - Tumor is anaplastic lymphoma kinase (ALK)-positive

**AND**

3 - Disease is relapsed or refractory

**AND**

4 - Used as palliative intent therapy or second-line and subsequent therapy

Product Name:Zykadia

|                 |                                                                                                                                                      |
|-----------------|------------------------------------------------------------------------------------------------------------------------------------------------------|
| Diagnosis       | Non-Small Cell Lung Cancer (NSCLC), Soft Tissue Sarcoma, Central Nervous System (CNS) Cancers, Histiocytic Neoplasms, Anaplastic Large Cell Lymphoma |
| Approval Length | 12 month(s)                                                                                                                                          |
| Therapy Stage   | Reauthorization                                                                                                                                      |
| Guideline Type  | Prior Authorization                                                                                                                                  |

**Approval Criteria**

1 - Patient does not show evidence of progressive disease while on Zykadia therapy

Product Name:Zykadia

|                 |                           |
|-----------------|---------------------------|
| Diagnosis       | NCCN Recommended Regimens |
| Approval Length | 12 month(s)               |

|                                                                                                                                                |                       |
|------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Therapy Stage                                                                                                                                  | Initial Authorization |
| Guideline Type                                                                                                                                 | Prior Authorization   |
| <b>Approval Criteria</b><br><br><b>1</b> - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium |                       |

|                                                                                                           |                           |
|-----------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name:Zykadia                                                                                      |                           |
| Diagnosis                                                                                                 | NCCN Recommended Regimens |
| Approval Length                                                                                           | 12 month(s)               |
| Therapy Stage                                                                                             | Reauthorization           |
| Guideline Type                                                                                            | Prior Authorization       |
| <b>Approval Criteria</b><br><br><b>1</b> - Documentation of positive clinical response to Zykadia therapy |                           |

## 2 . Revision History

| Date      | Notes                                                                                                                                                                                                     |
|-----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 3/26/2025 | Updated formularies. Removed ROS positive criteria from NSCLC as this is no longer an NCCN recommendation. Removed criteria for IM T which was duplicative as this is covered under soft tissue sarcoma s |

Zymfentra



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-163904                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Guideline Name</b> | Zymfentra                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Formulary</b>      | Medicaid - Community & State Colorado (ACUCO, ACUCOC)<br>Medicaid - Community & State Hawaii (ACUHI, ACUHIEC)<br>Medicaid - Community & State Maryland (ACUMD)<br>Medicaid - Community & State New Jersey (PSI2300)<br>Medicaid - Community & State New York (ACUNY, ACUNYM)<br>Medicaid - Community & State New York EPP (ACUNYEPP)<br>Medicaid - Community & State Pennsylvania CHIP (ACUPAC)<br>Medicaid - Community & State Rhode Island (ACURI) |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 2/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                        |                       |
|------------------------|-----------------------|
| Product Name:Zymfentra |                       |
| Diagnosis              | Ulcerative Colitis    |
| Approval Length        | 12 month(s)           |
| Therapy Stage          | Initial Authorization |
| Guideline Type         | Prior Authorization   |



**Approval Criteria**

**1** - Submission of medical records documenting clinical rationale for need of subcutaneous infliximab (Zymfentra) in place of infliximab administered intravenously (covered under the medical benefit)

**AND**

**2** - Diagnosis of moderately to severely active ulcerative colitis (UC)

**AND**

**3** - One of the following:

**3.1** Patient has been established on therapy with an infliximab product under an active UnitedHealthcare prior authorization for the treatment of moderately to severely active ulcerative colitis

**OR**

**3.2** Patient is currently on Zymfentra therapy for moderately to severely active ulcerative colitis as confirmed by claims history or submission of medical records

**AND**

**4** - Patient is not receiving Zymfentra in combination with a targeted immunomodulator [e.g., adalimumab, Entyvio (vedolizumab), Olumiant (baricitinib), Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), Stelara (ustekinumab), Xeljanz (tofacitinib)]

**AND**

**5** - Prescribed by or in consultation with a gastroenterologist

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                     |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Zymfentra                                                                                                                                                                                                                                                                                                                                                                                                                                               |                     |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Ulcerative Colitis  |
| Approval Length                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 12 month(s)         |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Reauthorization     |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Prior Authorization |
| <p><b>Approval Criteria</b></p> <p>1 - Documentation of positive clinical response to Zymfentra therapy</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Patient is not receiving Zymfentra in combination with a targeted immunomodulator [e.g., adalimumab, Entyvio (vedolizumab), Olumiant (baricitinib), Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), Stelara (ustekinumab), Xeljanz (tofacitinib)]</p> |                     |

|                                                                                                                                                                                                                                                                                                                                                                        |                       |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Product Name:Zymfentra                                                                                                                                                                                                                                                                                                                                                 |                       |
| Diagnosis                                                                                                                                                                                                                                                                                                                                                              | Crohn's disease       |
| Approval Length                                                                                                                                                                                                                                                                                                                                                        | 12 month(s)           |
| Therapy Stage                                                                                                                                                                                                                                                                                                                                                          | Initial Authorization |
| Guideline Type                                                                                                                                                                                                                                                                                                                                                         | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - Submission of medical records documenting clinical rationale for need of subcutaneous infliximab (Zymfentra) in place of infliximab administered intravenously (covered under the medical benefit)</p> <p style="text-align: center;"><b>AND</b></p> <p>2 - Diagnosis of moderately to severely active Crohn's disease (CD)</p> |                       |

**AND**

**3** - One of the following:

**3.1** Patient has been established on therapy with an infliximab product under an active UnitedHealthcare prior authorization for the treatment of moderately to severely active crohn's disease

**OR**

**3.2** Patient is currently on Zymfentra therapy for moderately to severely active crohn's disease as confirmed by claims history or submission of medical records

**AND**

**4** - Patient is not receiving Zymfentra in combination with a targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Entyvio (vedolizumab), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), Stelara (ustekinumab), Xeljanz (tofacitinib)]

**AND**

**5** - Prescribed by or in consultation with a gastroenterologist

|                                                                                                             |                     |
|-------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name:Zymfentra                                                                                      |                     |
| Diagnosis                                                                                                   | Crohn's disease     |
| Approval Length                                                                                             | 12 month(s)         |
| Therapy Stage                                                                                               | Reauthorization     |
| Guideline Type                                                                                              | Prior Authorization |
| <b>Approval Criteria</b><br><br><b>1</b> - Documentation of positive clinical response to Zymfentra therapy |                     |

**AND**

**2** - Patient is not receiving Zymfentra in combination with a targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Entyvio (vedolizumab), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), Stelara (ustekinumab), Xeljanz (tofacitinib)]

## 2 . Revision History

| Date      | Notes                                                        |
|-----------|--------------------------------------------------------------|
| 1/16/2025 | Added requirement for justification of subq infliximab vs IV |

Zyvox



## Prior Authorization Guideline

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Guideline ID</b>   | GL-242235                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Guideline Name</b> | Zyvox                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Formulary</b>      | Medicaid - Community & State Colorado (ACUCO, ACUCOC)<br>Medicaid - Community & State Hawaii (ACUHI, ACUHIEC)<br>Medicaid - Community & State Maryland (ACUMD)<br>Medicaid - Community & State New Jersey (PSI2300)<br>Medicaid - Community & State New York (ACUNY, ACUNYM)<br>Medicaid - Community & State New York EPP (ACUNYEPP)<br>Medicaid - Community & State Pennsylvania CHIP (ACUPAC)<br>Medicaid - Community & State Rhode Island (ACURI)<br>Medicaid - Community & State Virginia (ACUVA, ACUVAC, ACUVAEC)<br>Medicaid - Community & State New Mexico (ACUNM)<br>Medicaid - Community & State Pennsylvania (ACUPA) |

### Guideline Note:

|                 |          |
|-----------------|----------|
| Effective Date: | 6/1/2025 |
|-----------------|----------|

## 1 . Criteria

|                                              |                     |
|----------------------------------------------|---------------------|
| Product Name: Brand Zyvox, generic linezolid |                     |
| Guideline Type                               | Prior Authorization |

### Approval Criteria

**1** - For continuation of therapy upon hospital discharge

**OR**

**2** - As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication

**OR**

**3** - ONE of the following diagnoses:

Nosocomial pneumonia

Community-acquired pneumonia

Skin and skin structure infections (complicated and uncomplicated)

**OR**

**4** - Invasive infection caused by or likely to be caused by vancomycin-resistant *Enterococcus faecium* (VRE)

**OR**

**5** - The drug has been recognized for treatment of the indication by the Infectious Diseases Society of America (IDSA)

|       |                                                                                                                                                                                                                                                               |
|-------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Notes | Approval Duration: For vancomycin-resistant <i>Enterococcus faecium</i> , a uthorization will be issued for 28 days. For osteomyelitis, authorization will be issued for the requested duration, not to exceed 6 weeks. All o ther approvals are for 14 days. |
|-------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

## 2 . Revision History

UnitedHealthcare Community Plan of New Jersey – Clinical Pharmacy Guidelines

| Date      | Notes                 |
|-----------|-----------------------|
| 4/18/2025 | Combined formularies. |